

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

**IN RE: ETHICON, INC., PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY
LITIGATION**

**THIS DOCUMENT RELATES TO
WAVE 1 / TVT-S CASES**

Master File No. 2:12-MD-02327

**JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE**

RULE 26 EXPERT REPORT OF JERRY G. BLAIVAS, M.D.

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. My opinions are as follows:

I. QUALIFICATIONS

Dr. Blaivas is a board certified urologist in the state of New York. He attended Tufts College for his bachelor's degree in 1964 and Tufts University School of Medicine for his medical doctorate in 1968. He completed a urology residency in 1976 after completing a general surgery internship followed by a two year general surgery residency. He has been teaching medicine since 1976 at Tufts University School of Medicine, Columbia University, Cornell University and most recently, SUNY Downstate Medical School. Throughout his academic career, Dr. Blaivas remained a practicing surgeon in a number of hospitals in Massachusetts and New York, and is currently an attending surgeon at The New York Presbyterian Hospital and Lenox Hill Hospital.

Dr. Blaivas is one of the pioneers of sling surgery for women with sphincteric incontinence. He performed his first autologous rectus fascial sling operation in 1981 and shortly thereafter modified the technique by creating a fascial graft instead of a fascial flap which was the prevailing method at the time. The reason for this change is that the flap was tethered by its abdominal attachments such that it was very difficult to place the sling loosely enough to avoid causing urethral obstruction. Once that modification was adapted, it was much easier to place the sling without any tension at all and that principle became the guiding principle for the subsequent development of synthetic mesh slings. In 1998, Dr. Blaivas, in a peer review journal, proposed that rectus fascial sling be considered a suitable operation for all women with sphincteric incontinence. Prior to that time, it was considered to be indicated only in women with complicated problems who had failed prior incontinence operations.

In the 1980's, Dr. Blaivas became acquainted with severe complications that resulted from synthetic mesh slings composed of Marlex and Mersilene. He performed a number of surgeries to remove these slings because of severe, refractory complications including pain, infection, erosion and urinary fistula. So difficult and problematic were these complications that Dr. Blaivas traveled to Toronto and spent some time with Ted Morgan, MD – a gynecologist who performed the largest number of these operations in the peer review literature. Dr. Morgan was considered to be a highly qualified surgeon, but even in his hands devastating complications occurred and they often occurred years after the original surgery. In the hands of less skilled surgeons, the complication rate was much higher. Dr. Blaivas discussed the surgical technique of sling surgery and methods of treating complications in great detail with Dr. Morgan. He concluded that: 1) even in the hands of a master surgeon, devastating complications could occur with synthetic slings, but rarely if ever occurred with autologous fascial (graft) slings; 2) in the hands of inexperienced surgeons, the complication rate could be unacceptably high; 3) removal of the mesh was exceedingly difficult and fraught with its own complications; 4) once a complication occurred, the chances of a successful outcome are low; and 5) the mesh itself, because it is a foreign body, contributes significantly to the complication rate. Because of these known complications and the technical difficulties performing mesh surgery, the operation fell out of favor until synthetic slings were revived, reinvented and promoted by industry through pervasive advertising and inducements to physicians to perform such surgeries.

Dr. Blaivas himself was heavily “recruited” by manufacturers of synthetic slings to become a “key opinion leader” and promote sling surgery. He was thoroughly vetted by industry representatives and Peter Petros, MD, one of the pioneers of synthetic sling surgery, spent a week with him in New York at his office and in the operating room discussing and demonstrating the theory and surgical technique of synthetic sling surgery. It was during this period of time that Dr. Blaivas decided to perform some synthetic slings in highly selected patients because the procedure could be performed so quickly and with so small an incision. Once he became adept at the technique through simulated training, he realized that there really wasn't any need for the “sling kit” that was supplied by the manufacturer. Further, he thought that the technique of passing the trocars from the vagina upwards to the abdomen was a much more dangerous technique that could lead to adjacent organ injury. So, instead, he fashioned a strip of “Gynemesh” and used a Stamey needle to pass the trocars from the abdomen to the vagina. He further modified the technique to include dissection alongside the urethra into the retropubic space, nearly eliminating the possibility of injuring the bladder or urethra or adjacent organs with the trocars.

In essence, Dr. Blaivas was using exactly the same technique he used for rectus fascial slings (which was considered the gold standard for incontinence surgery) and simply replaced the rectus fascial graft with a synthetic graft. Dr. Blaivas considered that synthetic slings, using the technique described here, could actually improve sling surgery provided that the new meshes were improved to the point that they had an acceptable safety profile and, in fact, he opined that synthetic slings will become the standard once the bugs were worked out. But to date, that has not happened. Throughout this time (the last decade of the 20th and first decade of the 21st century), Dr. Blaivas became increasingly aware of devastating, life threatening, and life style altering complications of synthetic sling surgery and became a world renowned expert at treating those complications. He has personally operated on about 75 – 100 patients with severe synthetic mesh

complications, and taken care of hundreds more who either did not elect further surgery or who simply gave up and were seeking relief from pain management experts. He has also discussed these issues with his peers. It is that experience, supported by peer-reviewed scientific literature, which forms the basis of the following opinions.

In August, 2015, Dr. Blaivas published the review article, “Safety considerations for synthetic sling surgery” in Nature Reviews Urology. The Nature family of journals is regarded as one, if not *the* premier resource for scientific research in the world.¹ Publication in Nature Reviews Urology, requires that the article meet strict criteria.² In its final version, the article was a herculean project - naming nine authors, spanning 29 pages, and containing 397 references. The exhaustive research presented in this paper further supports the opinions.

All of these opinions are to a reasonable degree of medical certainty. He applied the same scientific rigor that he use in all aspects of his professional activities, including caring for patients, publishing, lecturing, consulting with other health care professionals, and serving as a litigation expert. The methodology he used in rendering my opinions is the same that he uses in his professional activities. His opinions have been consistent over time and do not differ just because they are provided for various purposes or audiences.

Dr. Blaivas’ Curriculum Vitae is attached hereto and by reference made a part hereof. Please see Exhibit “A” attached.

II. DISCUSSION OF OPINIONS

1. The Gynecare TVT-Secur System (“TVT-S”) is a polypropylene mesh product made and marketed by Ethicon to allegedly treat stress urinary incontinence (“SUI”). The TVT-S was the first single incision sling (“SIS”) made and marketed for treatment of SUI. The TVT-S differs from Ethicon’s earlier TVT-R and TVT-O in that it requires only a single incision to insert the device. Ethicon marketed the device as: “less invasive, less dissection, less anesthesia, and less pain”³ than the TVT-R and TVT-O. The TVT-S consists of a piece of polypropylene mesh measuring 1.1 cm x 8.0 cm and two stainless steel introducers. It was marketed by Ethicon between 2006 and 2012, when it was withdrawn from the market.

2. The TVT-S was significantly different than the TVT-R and TVT-O that had been marketed by Ethicon. It could be placed in either a “U” position or as a hammock through a single incision. I agree with Ethicon medical director, Dr. Robinson, who stated in 2007 that “[s]ince Secur clearly is a sling ‘unto itself’ as far as techniques go, much relearning had to occur to gain success in the

¹ “The Nature Reviews clinical journals commission leaders in the field to write clinical content of the highest quality, authority and accessibility. Content is subject to rigorous review by our in-house editors and/or peer-review, and counsel is provided by the Editors-in-Chief and an international Advisory Boards to ensure comprehensive coverage of topical issues.” Nature.com accessed 12/18/2015.

² The criteria for publication include: Timely, accurate and balanced; Important for practicing doctors, researchers and academics in the subspecialty; Interesting and accessible to practicing doctors, researchers and academics in wider specialties. Nature.com accessed 12/18/2015.

³ ETH.MESH.06860553

US and particularly in Europe.”⁴ I also agree with one of Ethicon’s KOLs statements that the “TVT Secur is so ‘utterly different to the other TVTs that it probably shouldn’t be called a TVT’ and the speed to market and breadth of the launch did not take this into account.”⁵

3. The Gynecare TVT-S should not have been designed for placement in a surgically contaminated field⁶ without proper animal and clinical studies to document safety and without a clear warning about the possibility of short and long term complications.⁷ Bacteria attaches to mesh during the insertion process and can cause both acute and chronic infections in women.⁸ Infection, even subclinical, can result in chronic inflammation, scarring, pain, abscess, vaginal, bladder and urethral erosion and other complications.

4. The Gynecare TVT-S causes serious and life-style altering complications including but not limited to chronic pelvic pain syndromes, chronic dyspareunia and sexual impairment, de novo urinary symptoms, infections, urethral obstruction, pelvic organ dysfunction, pelvic anatomy distortion, and other complications.⁹ Ethicon was aware of these complications at the time it was marketing the TVT-S.¹⁰ These complications often require reoperation and are sometimes

⁴ ETH.MESH.00832210

⁵ ETH.MESH.00845371

⁶ E.g., Culligan P, Heit, M., Blackwell, L., Murphy, M., Graham, C. A., & Snyder, J. Bacterial colony counts during vaginal surgery. *Infectious Diseases in Obstetrics and Gynecology*. 2003;11(3):161-5.

⁷ E.g., Vollebregt A, Troelstra, A., & van der Vaart, C. H. . Bacterial colonisation of collagen-coated polypropylene vaginal mesh: are additional intraoperative sterility procedures useful? *International Urogynecology Journal and Pelvic Floor Dysfunction*. 2009; 20(11):1345-51; Choi JJ, Palaniappa, N. C., Dallas, K. B., Rudich, T. B., Colon, M. J., & Divino, C. M. Use of Mesh During Ventral Hernia Repair in Clean-Contaminated and Contaminated Cases. *Annals of Surgery*. 2012;255(1):176-80.

⁸ E.g., Vollebregt, 2009; Choi, 2012; Klinge U, Klosterhalfen, B., Muller, M., Ottinger, A. P., & Schumpelick, V. Shrinking of polypropylene mesh in vivo: an experimental study in dogs. *The European Journal of Surgery*. 1998;164(12):965-9.

⁹ E.g., Blaivas JG, Purohit, R. S., Weinberger, J. M., Tsui, J. F., Chouhan, J., Sidhu, R., & Saleem, K. Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications. *The Journal of Urology*. 2013;190(4):12816; Blaivas JG, Mekel G. Management of Urinary Fistulas Due to Midurethral Sling Surgery. *Journal of Urology*. 2014; Blaivas JG, Purhoit RS. Post-traumatic female urethral reconstruction. *Curr Urol Rep*. 2008;9(5):397-404; Petri E, Ashok K. Comparison of late complications of retropubic and transobturator slings in stress urinary incontinence. *Int Urogynecol J*. 2012;23(3):321-5; Abbott S, Unger CA, Evans JM, Jallad K, Mishra K, Karram MM, et al. Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study. *American journal of obstetrics and gynecology*. 2014;210(2):163 e1-8; Hansen BL, Dunn GE, Norton P, Hsu Y, Nygaard I. Long-term follow-up of treatment for synthetic mesh complications. *Female pelvic medicine & reconstructive surgery*. 2014;20(3):126-30; Unger CA, Abbott S, Evans JM, Jallad K, Mishra K, Karram MM, et al. Outcomes following treatment for pelvic floor mesh complications. *Int Urogynecol J*. 2014;25(6):745-9; Rogo-Gupta L, Raz S. Pain Complications of Mesh Surgery. In: Goldman HB, editor. *Complications of Female Incontinence and Pelvic Reconstructive Surgery*. Current Clinical Urology. p. 87-105; Shah K, Nikolavsky D, Gilsdorf D, Flynn BJ. Surgical management of lower urinary mesh perforation after mid-urethral polypropylene mesh sling: mesh excision, urinary tract reconstruction and concomitant pubovaginal sling with autologous rectus fascia. *Int Urogynecol J*. 2013;24(12):2111-7; Dunn GE, Hansen BL, Egger MJ, Nygaard I, Sanchez-Birkhead AC, Hsu Y, et al. Changed women: the long-term impact of vaginal mesh complications. *Female pelvic medicine & reconstructive surgery*. 2014;20(3):131-6; Hammett J, Peters A, Trowbridge E, Hullfish K. Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery. *Int Urogynecol J*. 2014;25(4):465-70; Tomaselli GA, et al. Tension-free vaginal tape-obturator and tension-free vaginal tape-Secur for the treatment of stress urinary incontinence: a 5-year follow-up randomized study. *Eur J Obstet Gynecol Reprod Biol*. 2015 Feb; 185:151-5.

¹⁰ ETH.MESH.01059148

permanent. Because of these complications, the risks of these devices outweigh the benefits. Many of these complications can occur many years or even decades after the original surgery.¹¹

5. The management of many sling complications is fraught with complexity and results in a high rate of persistent symptoms.¹² This has been evident since the complications from the Mersilene, Marlex, Gore-Tex, and Protogen slings that were performed during the last three decades of the 20th century and more recently the Protegen and Mentor ObTape slings. Further Ethicon knew or should have known about the contemporaneous complications that were occurring with their devices and with the devices of their competitors. From a scientific and ethical perspective, Ethicon should have had a high index of suspicion relating to the product defects based on the previous experiences with other synthetic products.

6. One of the most debilitating and challenging complication to treat is chronic pain. This pain can be located in the abdomen, pelvis, vagina, buttocks, perineum, groin, thigh, or leg. It can be acute (occurring immediately after surgery) or chronic with an insidious onset. It is often refractory to traditional treatments. It can be related to erosion; scarring; mesh deformation; entrapment or compression of large nerves with classic or atypical nerve distribution; entrapment of smaller nerve branches with diffuse distribution; muscular inflammation, scarring, trauma, and hypertonicity; visceral pain syndromes; and other complications. It can be associated with other sensory changes such as numbness and tingling.

7. Chronic Mesh Pain Syndrome (CMPS) has been described in the medical literature. The syndrome is characterized by the transformation of vaginal pain into a multi-organ system process. The pain is considerably greater and lasts longer than routine post-operative pain and treatment is extremely challenging.¹³ The pain may continue, or even worsen, after mesh excision or revision. Completely new treatment modalities for pelvic pain have been developed as a response to this pain management challenge, including trigger point injections, nerve blocks, Botox injection, pelvic floor physical therapy, treatment with medications for chronic, neuropathic pain, and referral to contract-based pain management programs. These were extremely rarely used in urology or gynecology until the appearance of mesh-related pain.¹⁴

8. The TVT-S is defective because it causes a greater number of complications and was less effective than other midurethral polypropylene slings.¹⁵ One study showing a 42% failure rate

¹¹ Blaivas, 2015; ETH.MESH.18656464; ETH.MESH.18656973; ETH.MESH.18659067; ETH.MESH.18660347; ETH.MESH.18886712; ETH.MESH.18660993; ETH.MESH.18887347.

¹² E.g., Deng DY, Rutman, M., Raz, S., & Rodriguez, L.V. Presentation and management of major complications of midurethral slings: Are complications underreported? *Neurourology and Urodynamics*. 2007;26(1):46-52.

¹³ E.g., Rogo-Gupta, 2013.

¹⁴ E.g., Petri, 2012; Rogo-Gupta, 2013; Ross S, Robert M, Swaby C, Dederer L, Lier D, Tang S, et al.

Transobturator tape compared with tension-free vaginal tape for stress incontinence: a randomized controlled trial. *Obstetrics and gynecology*. 2009;114(6):1287-94; Chohan HJ, Hutchings TB, Rooney KE. Dyspareunia associated with paraurethral banding in the transobturator sling. *American journal of obstetrics and gynecology*;202(5):481 e1-5; Boyles SH, Edwards R, Gregory W, Clark A. Complications associated with transobturator sling procedures. *Int Urogynecol J Pelvic Floor Dysfunct*. 2007;18(1):19-22; Parnell BA, Johnson EA, Zolnoun DA. Genitofemoral and perineal neuralgia after transobturator midurethral sling. *Obstetrics and gynecology*. 2012;119(2 Pt 2):428-31

¹⁵ Hota, Lekha S., MD, *et al.* TVT-Secur (Hammock) Versus TVT-Obturator: A Randomized Trial of Suburethral Sling Operative Procedures. *Female Pelvic Med Reconstr Surg*. 2012, Jan-Feb; 18(1): 41-45 (47% cure rate with TVT-S and 91% cure rate with TVT-0); Maslow K, Gupta C. Randomized clinical trial comparing TVT Secur system and

with the TVT-S concluded that “[O]ur experience shows that despite its good short-term efficacy, TVT-Secur is associated with a high recurrence rate of SUI. Therefore, TVT-Secur does not seem appropriate for SUI first-line management in women.”¹⁶

9. This is also supported by internal Ethicon documents. In an unpublished Ethicon Clinical Study Report issued after the first 12-month human data available on the TVT-S, there were a total of 51 adverse events reported in 32 out of 72 patients. One of the “safety conclusions” was that “[o]nly 69.4% subjects experienced no major device-related complications.”¹⁷ It went on to note “[o]nly 55% of the women reported no leak on self-assessment [the *subjective* cure rate].” The summary concluded “[i]n the future, well planned randomized studies will have to be conducted in order to discern if the new single-incision procedures can achieve the same level of effectiveness as has been extensively shown with the TVT procedure and (with shorter follow-up) also with the TVT-O procedure. . . . As long as complications occur at the rate seen in this study . . . the single-incision procedure cannot be recommended as a first line treatment for [SUI].” In fact, Ethicon’s internal documents showed that surgeons in 2007 were experiencing “high ‘failure’ rates across multiple centres.”¹⁸ Other physicians were reporting very low rates of success in their operations to Ethicon. At least one advised of results that Ethicon called “concerning”: “over 50% of his patients being in the unchanged or worsened category and no more than 20% being dry. In addition, he told our country director in Germany that he received calls from others surgeons in Germany who are facing similar problems of efficacy.”¹⁹

10. These and other complications may occur even in experienced hands and when proper surgical technique is used. Ethicon’s marketing materials suggest that these complications occur mostly because of faulty surgical technique performed by inexperienced or poorly trained surgeons, perhaps by “over-tensioning” or misplacement. In the majority of cases that I see in my practice and that are reported in the literature, the device was placed in accordance with the manufacturers recommendations for placement.

11. Furthermore, the location of anatomical structures varies from individual to individual and even in the same individual, making accurate placement unpredictable. There is no such thing as “normal anatomy.” For example, positioning of the patient in various degrees of dorsal lithotomy position can impact the locations of nerves and blood vessels relative to surface landmarks. Since the Gynecare TVT-S normally passes dangerously close to vital structures, the anatomic and positional variations render trocar passage more hazardous than theoretic considerations would suggest.²⁰ Further, although bleeding can usually be controlled or is self-limited, nerve injuries can have disastrous long term consequences.

trans vaginal obturator tape for the surgical management of stress urinary incontinence. *Int Urogynecol J* (2014) 25:909–914 (63% cure rate with TVT-S and 86% cure rate with TVT-O); Nambiar A, *Single-incision sling operations for urinary incontinence in women*. Cochrane Database of Systematic Reviews 2014, Issue 6.

¹⁶ Cornu JN, Sèbe P, Peyrat L, Ciofu C, Cussenot O, and Haab F. (2010) “Midterm prospective evaluation of TVT-Secur reveals high failure rate.” *Eur Urol*. 2010 Jul; 58(1):157-61.

¹⁷ ETH.MESH.02916532

¹⁸ ETH.MESH.00642325

¹⁹ ETH.MESH.00840018; also ETH.MESH.03845464

²⁰ E.g., Bhoyrul, 2001; Shindel, 2005

12. In particular, the new technique introduced by Ethicon for use with the TVT-S caused additional problems with the device, including high failure rates. This was compounded by an IFU that did not adequately instruct physicians on how to implant the product. On November 2, 2007, Dr. Maree noted “[i]t is my understanding that some suggestions had come out in the form of (i) increased tension required with this mesh with ‘pillowing of peri-urethral tissues required,’ (which is quite the opposite of TVT-O recommendations), as well as (ii) new tips and tricks to avoid dislodging the device when removing the inserters and (iii) new tips for minimal dissection when introducing the product. We also discussed the fact that at this time some or all of these suggested changes may not be incorporated into the [IFU] or technical training material.”²¹ These tips were never included in the IFU for the TVT-S.

13. In my opinion, the TVT-S IFU is inadequate and does not adequately address techniques for implanting the TVT-S in women. According to Axel Arnaud at Ethicon: the TVT-S IFU is “not really surgeon's friendly as the two procedures are closely imbricated and this makes it uneasy for a surgeon to read and keep in mind. It is also missing details regarding optimal dissection and tensioning of the tape.”²² Similarly, Ethicon internally recognized that “Although we told surgeons how TVT SECUR needed to be set, they just were not ready to believe us, the sale force was not confident due to early failures, we did not have data to support the thinking, we (Ethicon) never before told surgeons how to set the mesh tension, because there is no one setting!”²³

14. Ethicon was also aware that surgeons were experiencing high rates of certain complications, including strong bleeding and/or haematoma. Ethicon also stated that: bleeding and/or haematoma “is the most risky for us. One patient went to another hospital, tape has to be removed and haematoma treated. We intensify the contact when we hear about those cases, but when the patient is going to another hospital or the physician is not informing immediately and frankly, it's difficult to get a clear picture. First explanations from our physicians: Risk to harm vessels or structures with a blade of this size is much higher than with a needle.”²⁴

15. Ethicon also recognized the difficulty surgeon's had with implanting the product, even surgeons who had been trained by Ethicon. As Ethicon observed: “Difficulty: what surgeons said they were doing and what we observed them doing were not the same thing.”²⁵ Even after attempting to revise the surgeon training materials and program, Ethicon internally recognized that many surgeons had “high initial post procedure incontinence rates . . . [and training with a KOL] still yields < 50% success rate.”²⁶ Similarly, according to Axel Arnaud, European Science Director at Ethicon: “The reality of the field is that some surgeons, including KOL's who have been correctly trained and who have passed the learning phase, are raising concerns about the efficacy of TVT Secur. They have hard time to achieve consistently good results with the device.”²⁷ One surgeon, who Ethicon considered “the most major GYN player . . . in British Columbia” told Ethicon representatives that the TVT-S was a “‘crappy device.’”²⁸

²¹ ETH.MESH.00832121. *See also* Aran Maree Depo, 7.22.13, 137:8-16.

²² ETH.MESH.01000726

²³ ETH.MESH.09951087

²⁴ ETH.MESH.03921612

²⁵ ETH.MESH.01758770

²⁶ ETH.MESH.01758770

²⁷ ETH.MESH.01000726

²⁸ ETH.MESH.00811030

16. I also have reviewed internal Ethicon documents concerning the training programs by Ethicon for the TVT-S and agree that such programs were inadequate. For example, In December 2006, Dr. Axel Arnaud stated that even surgeons “who have been correctly trained and who have passed the learning phase, are raising concerns about the efficacy of the TVT Secur . . . They are asking for clear recommendations about the way to perform the procedure, in particular about the size of the dissection, the tension to be given to the tape and the way to perform a cough test,”²⁹ none of which were disclosed in the TVT-S IFU.³⁰ Similarly, Dr. Maree stated that the “original (and current?) training program may not result in competency in device insertion or result in clinical efficacy. There appear to be ‘tricks’ to insertion of the product and removal of the inserters which prevent dislodging the device in the process.”³¹ I agree with Dr. Maree that “the average practitioner finds it too complicated to insert correctly pr cannot master the process.”³²

17. The high complications and low efficacy of the TVT-S device led Ethicon to stop marketing the TVT-S in Australia and New Zealand in 2007: “Given this fact and the clinical experience to date we have decided to cease marketing of TVT Secur in Australia and New Zealand pending our ability to create a sound program of preceptorships, obtaining the necessary clinical evidence and having what I would consider to be a solid program for launch.”³³ A dear doctor letter was mailed in March 2008, explaining the concerns expressed by many surgeons.³⁴ Ethicon did not discontinue the sale of TVT-S in the United States until 2012.

18. Even the simplest complications are often more complicated than they appear. It is commonly stated that when there is extrusion of the mesh through the vaginal wall, it is quite a simple thing to just trim the edges of the exposed sling and either create small vaginal wall flaps to cover the defect or simply leave the wound open and apply estrogen. However, the studies that report successful outcomes generally have a short follow-up and the outcomes may be much worse than they appear.³⁵ In my own personal experience, I have seen many patients who were treated this way who came back months, years, and even decades later with more extrusions and granulomas that proved almost impossible to “cure.”³⁶ These persistent and recurrent erosions are also reported in the medical literature and in Ethicon’s own documents.³⁷

19. Given the increasing number of mesh sling operations performed and the complexity of surgery to repair the complications, there are an increasing number of patients who have failed initial treatments and an increasing number of “mesh cripples”. As more slings implantations are being performed and the longevity expectations of patients are increasing, it has become apparent

²⁹ ETH.MESH.01000726

³⁰ ETH.MESH.02340568

³¹ ETH.MESH.00642325

³² ETH.MESH.00642325

³³ ETH.MESH.00845196

³⁴ ETH.MESH.04127238.

³⁵ E.g., Blaivas, 2015

³⁶ E.g., Reynolds WS, Kit, L., Kaufman, M.R., Karram, M., Bales, G.T., and Dmochowski, R. Obturator Foramen Dissection for Excision of Symptomatic Transobturator Mesh. The Journal of Urology. 2012;187(5):1680-4.; Blaivas, 2013

³⁷ E.g., Petri, 2012; Abbott, 2014; Hansen, 2014; Unger, 2014; Rogo-Gupta, 2013; Shah , 2013; Dunn, 2014; Hammett, 2014; ETH.MESH.01706065 at 3.

that unanticipated, serious, and sometimes lifestyle- altering complications can occur that are not only unique to patients with slings but are also often refractory to treatment.³⁸ Other authors of recent peer-reviewed articles agree. Lee states that the use of synthetic material has generated novel complications, including mesh extrusion, pelvic and vaginal pain and mesh contraction, requiring a new classification system for complications relating to prosthesis insertion. He coined the term “Meshology” – an evolving field of sub-specialization dedicated to a growing population of affected women with complications from synthetic materials.³⁹ Barski also described mesh-related complications as “a current emerging problem, which confronts all urologists and gynecologists in their daily practice.”⁴⁰

20. Removal of the Gynecare TVT-S is technically difficult and requires considerable surgical expertise that many implanting surgeons do not possess. Due to tissue ingrowth, it is very difficult and sometimes impossible to remove the entire mesh and, in most instances, there are remnants of mesh that remain. This is well documented in the medical and scientific literature.⁴¹ Further, there is a high likelihood of injuring adjacent structures and failing to alleviate symptoms, especially those related to pain, during removal surgery. There is a high incidence of recurrent sphincteric incontinence, requiring yet another procedure to repair it – ideally an autologous sling. Remnants of the partially removed Gynecare TVT-S can also migrate.⁴² All of these procedures create more scar tissue in the pelvis, which further compromises the functionality of the pelvic anatomy and causes additional complications for women.

21. The Gynecare TVT-S is not safer than the alternative procedures. Ethicon’s own documents show that “In comparison since launch in Aug 2006, TVT-SECUR does have significantly higher complaint rate then pre-existing products.”⁴³ Furthermore, I have seen no evidence that Ethicon studied or evaluated the safety and efficacy of the insertion technique it developed and sold as part of the Gynecare TVT-S device or researched potential alternatives to minimize complications.

22. Pubovaginal slings using autologous fascia is more effective than the Gynecare TVT-S. In my own personal series and according to several peer review meta-analyses and the AUA guideline panel the success rate for autologous slings is comparable to synthetic mesh slings⁴⁴ but the TVT-S has a much lower cure rate than other polypropylene midurethral synthetic slings.⁴⁵

23. Pubovaginal slings using autologous fascia are safer than synthetic slings with respect to serious complications such as lifestyle altering pain, dyspareunia, vascular, erosion, bowel and

³⁸ Blaivas 2015, 481.

³⁹ Lee 2015, 202.

⁴⁰ Barski and Deng 2015, p6.

⁴¹ E.g., Blaivas, 2015; Blaivas, 2013; Shah, 2013.

⁴² E.g., Blaivas, 2015

⁴³ ETH.MESH.01758770

⁴⁴ E.g., Ogah, J., Cody, D. J., & Rogerson, L. (2011). Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: a short version Cochrane review. *Neurourol Urodyn*, 30(3), 284-291. doi: .1002/nau.20980; Wadie, B. S., Edwan, A., & Nabeeh, A. M. (2005). Autologous fascial sling polypropylene tape at short-term followup: a prospective randomized study. *J Urol*, 174(3), 990-993. doi: .1097/01.ju.0000169492.96167.fe; Garcia-Urena, 2007

⁴⁵ ETH.MESH.01706065 at p. 27

lower urinary tract injury, and other complications. Although the reported incidence of urinary retention is slightly higher, much of the data to support that comes from an era before the importance of a tension free repair was known. Using current technique, urinary retention is comparable amongst autologous and synthetic slings.⁴⁶

24. These types of serious complications do not occur or occur very rarely in the alternative surgical treatments for stress urinary incontinence (such as autologous fascia pubovaginal slings or the Burch procedure). Furthermore, when complications occur with pubovaginal slings using autologous fascia, they are easier to treat and rarely if ever result in the permanent, lifestyle altering complications mentioned above. In addition, when mesh is not involved, it is almost always possible to obtain a satisfactory result treating the complication, unlike the Gynecare TVT-S.⁴⁷

25. In my own experience, performing thousands of rectus fascial slings, I have never injured the bladder, urethra, ureter or any adjacent organs except for two minor urethral injuries in women who had undergone multiple prior incontinence surgeries nor have we reported any nor have we reported any injuries in our case series.⁴⁸ Further, as a surgeon “of last resort” I have had the opportunity to care for at least a thousand women with complications of biologic slings, retropubic suspensions and vaginal repairs of incontinence and almost never have I seen complications of the magnitude of synthetic mesh sling complications that have become routine in my practice.

26. As a practicing surgeon, educator, academician, and editor/reviewer of scientific journals, I became aware of serious complications associated with synthetic mesh earlier than physicians in community practice. I first became aware of a death from a TVT sling approximately in 2000, but I already was including this fact in postgraduate lectures by 2002. The source of the information was first hand from the surgeon who performed the TVT. Industry (including Ethicon) representatives were present at meetings in which these complications were discussed by me and my colleagues. In addition, case reports appeared in the literature relatively soon after introduction of these devices and before clinical trials were completed. Further, complications appeared in the MAUDE database. As evidenced by Ethicon’s written materials, Ethicon downplayed these complications.

27. There is almost always a time lag between what is known by Industry and physicians such as myself and community physicians. This is due to the time it takes for the dissemination of information and the withholding of information by Ethicon. Community doctors are often unable to keep up with the vast amount of and rapid changes in the scientific literature. They generally rely on manufacturers, through their sales and other representatives, to provide complete and accurate information to them. Based on my interactions with company representatives (including Ethicon), and company (including Ethicon) promotional materials, synthetic slings were invariably described as effective, quick, having few complications, and easy to learn and perform.

⁴⁶ E.g., Blaivas, J. G., & Chaikin, D. C. (2011). Pubovaginal fascial sling for the treatment of all types of stress urinary incontinence: surgical technique and longterm outcome. *Urol Clin North Am*, 38(1), 7-15, v. doi: .1016/j.ucl.2010.12.002; Garcia-Urena, 2007.

⁴⁷ E.g., Blaivas, 2011; Blandon, R., Gebhart, J., Trabuco, E., & Klingele, C. (2009). Complications from vaginally placed mesh in pelvic reconstructive surgery. *Int Urogynecol J* 20, 523-531. doi: 10.1007/s00192-009-0818-9.

⁴⁸ E.g., Blaivas, 2011.

28. Mesh complications are significantly under-reported.⁴⁹ Additionally many, if not most, patients who experience complications do not return to their original implanting surgeons, contributing to a misperception among individual physicians that their outcomes are better than they, in fact, are.

29. Ethicon did not adequately warn doctors and patients about the possibility of serious, chronic and lifestyle altering nature of the complications associated with its products, such as the Gynecare TVT-S, which included chronic and debilitating pain, chronic dyspareunia and sexual dysfunction, nerve injuries/entrapment, groin and leg pain, vaginal scarring, bladder dysfunction, bladder stones, recurrent urinary or bladder infections, refractory overactive bladder and refractory sphincteric incontinence, the need for multiple corrective surgeries that may not resolve the symptoms⁵⁰, the marked difficulty removing the mesh sling and that even worse complications may ensue from mesh removal, the difficulties that occurred in treating the worsening of SUI following sling removal, and others. Ethicon did not adequately warn physicians about the possibility that the complications above, including erosion, could occur months or years or decades after placement of a synthetic sling, such as the Gynecare TVT-S.⁵¹

30. Ethicon did not adequately warn doctors and patients about the difficulty removing their products, such as the Gynecare TVT-S, nor did it warn them about the suboptimal and unpredictable results when mesh excision or revision becomes warranted due to complications. Very significantly, Ethicon did not attempt to train or educate doctors on how to best treat complications when they occur.⁵²

31. Ethicon concealed information that the SIS procedure, the procedure used for the TVT-S, had lower efficacy than the retropubic procedures. In a draft version of the TVT Abbrevio Professional Education PowerPoint, there is a slide that reports on a study showing lower efficacy and the slide has a note "I don't like this slide. We need to be careful to not disrupt the TVT Secur users **DELETE SLIDE.**"⁵³ The approved final version of this PowerPoint does not contain that slide.⁵⁴

32. The design of the Gynecare TVT-S is flawed because the product's IFU does not accurately represent the nature of the inflammatory response and resulting scar tissue. Instead, the TVT-S IFU states that "Animal studies show that implantation of PROLENE mesh and the absorbable fleece sandwich material made from VICRYL and PDS yarn elicit a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of

⁴⁹ E.g., Deng, 2007; Anger JT, Litwin, M. S., Wang, Q., Pashos, C. L., & Rodriguez, L. V. . Complications of sling surgery among female Medicare beneficiaries. *Obstetrics & Gynecology*. 2007;109(3):707-14; Blaivas, 2015; Dunn, 2014

⁵⁰ Depo of David Robinson, M.D 7.24.13 Page 355 Line 16 – Page 356 Line 8

⁵¹ ETH.MESH.02340568

⁵² Blaivas, J. G., Purohit, R. S., Weinberger, J. M., Tsui, J. F., Chouhan, J., Sidhu, R., & Saleem, K. (2013). Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications. *J Urol*. doi: 10.1016/j.juro.2013.03.044; Unger, C., Abbot, S., Evans, J., Jallad, K., Mishra, K., Karram, M., Iglesia, C., Rardin, C., Barber, M. Outcomes following treatment for pelvic floor mesh complications. *Int Urogynecol J*. DOI 10.1007/s00192-013-2282-9.

⁵³ ETH.MESH.01201957

⁵⁴ ETH.MESH.00174033

tissue, that can grow through the interstices of the mesh system as the fleece portion is being absorbed, thus incorporating the mesh into adjacent tissue. The PROLENE material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes." Despite literature to the contrary and the recommendations of its own employees, Ethicon never changed the IFU to reflect: 1) the inflammatory response is persistent and not transient; and 2) the mesh creates dense scar tissue not a "thin fibrous layer of tissue."⁵⁵

33. The design of the TVT-S is also flawed because the product's IFU does not accurately and completely represent the nature of the potential complications that women can suffer. Ethicon, through its medical director, was aware of potential complications associated with the TVT-S device as early as 2005 and included those complications in a Clinical Expert Report ("CER") for the TVT-S, an internal document only available to Ethicon.⁵⁶ Several of these complications were omitted from the TVT-S IFU. Similarly, in October, 2005, a protocol for the Pilot Study of the TVT-S was produced which contained a list of anticipated complications identical to those contained in the CER.⁵⁷ Again, this information was not contained in the IFU, the only document which the public would receive warning of adverse events or potential complications associated with the TVT-S.⁵⁸ Medical Director Dr. Weisberg also testified that Ethicon did not include: "permanent, lifelong, worsening and debilitating pain," lifelong risk of surgical repairs for erosions, "severe or chronic inflammation," fibrotic bridging, that the product can degrade, or cause severe erosion.⁵⁹

34. The design of the TVT-S is flawed because the product's IFU Adverse Reactions section does not warn of the possibility of dyspareunia, chronic pelvic pain, and multiple surgical interventions to treat erosion, which were known adverse reactions according to internal Ethicon documents.⁶⁰

35. In addition, the IFU incorrectly states that the TVT-S is "tension-free." In reality, it is extremely difficult to correctly "tension" the sling. If placed even slightly too snugly, the tape may cause temporary or permanent lower urinary tract obstruction. This is compounded and the problems increase over time as the TVT-S shrinks in a woman's body. On the other hand, if the sling is applied too loosely, incontinence will persist. I agree with one of Ethicon's KOLs Key Opinion Leaders ("KOLs") when he gave "his opinion that the 'IFU is fundamentally misleading.' Tension-free, tension-less and placement with no tension are complete misnomers."⁶¹ Ethicon also internally acknowledged in 2007 that "mesh tensioning [for the TVT-S] is different than kits with sheaths."⁶²

36. The IFU is also inadequate in that it represents complications as "transitory":

⁵⁵ ETH.MESH.02340568

⁵⁶ ETH.MESH.01037447; Deposition of Charlotte Owens 6.19.13 Page 178 Line 10-14.

⁵⁷ ETH.MESH.00538202

⁵⁸ Deposition of Charlotte Owens, MD 6.19.13 Page 204 Line 14-19; Deposition of Charlotte Owens MD 6.19.13 Page 212 Line 7-213 Line 1; 214 Line 5-13.

⁵⁹ Weisberg Dep. (8/9/13) 968:12-972:21.

⁶⁰ ETH.MESH.04081189; ETH.MESH.04081301; David Robinson Dep. at 251:7-12; Deposition of David Robinson, M.D 7.24.13, 355:16-356:8.

⁶¹ ETH.MESH.00845371

⁶² ETH.MESH.03922618

Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.⁶³

This language is not correct – the complications can be permanent, not transitory as Ethicon states. I agree with Ethicon’s Associate Medical Director of Worldwide Customer Quality Meng Chen, M.D., who stated “Pardon me again, from what I see each day, these patient experiences are not “transitory” at all.”⁶⁴

37. Published reports on long-term outcomes of patients after mesh removal surgery are limited. Most authors of studies in this area commented on the technical difficulties encountered during mesh excision surgery and the fact that many (and in some series, most) patients require two or more surgeries; thus, even in the short term, outcomes are often suboptimal. Beyond the immediate intra-operative risks lays ahead the concern for secondary urinary incontinence and its management. At least one-third of patients undergoing sling excision surgery develop recurrent SUI. Treatment of persistent pain in patients with a SMUS is particularly challenging and has been entirely empirical and progressive in nature. Chronic disabling pain is one of the most common indications for mesh removal⁶⁵ Barski also described the difficulty treating pain caused by mesh slings with only 28% reporting a relief of symptoms postoperatively. Particularly difficult and traumatic for the pelvic floor were the excisions of transobturator tapes, according to the Barski review.⁶⁶ Lee also described pelvic pain and dyspareunia (up to 24% following MUS) as a “most distressing and potentially irreversible complication to treat.”⁶⁷ The etiology of chronic pain after MUS surgery is multifactorial. A complex interplay of factors can be causative, including synthetic material type, nerve and muscle injury, infection, contraction, erosion or extrusion.⁶⁸

38. Ethicon would have known about these serious complications if proper clinical trials had been performed. Appropriate and unbiased clinical testing, if performed, would have shown the problems and complications associated with synthetic slings, like the Gynecare TVT-S. Because of the known complications, many occurring years after the original surgery, well conducted, long term clinical trials (or a registry) would have demonstrated the extent and nature of these devastating complications.

39. Ethicon was aware that its own consultants and surgeons were concerned about launching the TVT-S without any clinical trials. In an June 20, 2006 email, Ethicon employees stated: “Regarding the proposed RCT - Both Prof. Nilsson and Prof. Artibani expressed their worries about us launching TVT SECUR with no clinical data (other than the 50 patients, 5 weeks follow up) Moreover, during my meeting last week with Prof. Artibani I was faced again with the issue of launching SECUR with very limited clinical data.”⁶⁹ Ethicon convinced both of those Key Opinion Leaders (“KOL”) to support the launch by telling them that it had a plan to conduct

⁶³ ETH.MESH.02340568. Also Weisberg dep. (8/9/13) 968:2-969:10; Robinson Dep. (9/11/13) 329:12-330:7

⁶⁴ ETH.MESH.04093125.

⁶⁵ Blaivas 2015, 494.

⁶⁶ Barski and Deng 2015, p6.

⁶⁷ Lee 2015, 202.

⁶⁸ Lee 2015, 205.

⁶⁹ ETH.MESH.03172197

a Randomized Controlled Trial: “He was very impressed that we are launching this system and already have plans to support it clinically, both for the short and long term. Both of them, mostly due to our future plans, are willing to assist us with our communication plans with SECUR across the region. I truly believe we have two outstanding leading KOL that can really assist with the success of this system across EMEA.”⁷⁰ However, Ethicon cancelled the RCT for Secur, despite concerns raised about doing so: “I’m a bit concern that by canceling the RCT we will hurt our image in their eyes, especially after we’ve communicated this to them and worked with them to resolve any concerns they had associating with TVT SECUR. I believe that the success of the launch of TVT SECUR across EMEA (and probably other parts WW) will depend heavily on those two KOL and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT.”⁷¹

40. In reality, an Ethicon PowerPoint revealed:

- TVT SECUR was launched WW on Sep. 2006
 - No long term human use data to support launch
 - Commitment to 6 investigators for a post-launch RCT
- Upon launch
 - Decision not to start RCT (budget constrains)
 - Noise around the launch with no clinical data
 - Internally/Externally
 - Demand internally and externally for data collection to support launch.⁷²

41. Ethicon belatedly recognized that it should have conducted clinical trials before launching the TVT-S. In 2007, it stated (in connection with its TVT-S experience) that the “learnings from a first human use trial should be gathered, digested, and the device/training adjusted accordingly before launch.”⁷³ Similarly, it also cautioned (after the launch of the TVT-S) that: “We will also need to check that new products, when either significantly modified from predecessors or which bring with them a substantially new technique, have adequate pre-market safety and efficacy clinical data to justify their launch.”⁷⁴ This was not done for the TVT-S.

42. Ethicon also internally recognized that many recognized that the TVT-S was rushed to market in the absence of clinical support for the product. One Ethicon PowerPoint stated: “Belief by many physicians that Ethicon rushed TVT-Secur to market in the absence of sound clinical data - Left physician customers vulnerable to inferior clinical outcomes (quite frequently mentioned in most markets).”⁷⁵

43. The medical literature surrounding the Gynecare TVT-S and other synthetic slings, is seriously flawed for reasons including, but not limited to, industry sponsorship, researcher bias,

⁷⁰ ETH.MESH.03172197

⁷¹ ETH.MESH.03172197

⁷² ETH.MESH.00134794

⁷³ ETH.MESH.01758770

⁷⁴ ETH.MESH.00642325 p. 7

⁷⁵ ETH.MESH.03643186 p. 39

publication bias, industry manipulation of data, inappropriate choice of outcome variables, and lack of long-term follow-up.⁷⁶ In the Nature review, we noted the poor quality of many of the studies assessing risks of SMUS-associated complications. Deficiencies include the absence of sufficiently explicit outcome data due to the validation instruments used, the lack of long-term data, the loss of patients to follow-up, and the failure to distinguish between different products - to name a few. The poor quality of many of the studies on SMUS has been confirmed by other authors as well. Brubaker reported on missing data in two large SUI trials, TOMUS and SISTEr.⁷⁷ Barski, in performing the meta-analysis on mesh complications, found no randomized trials on the surgical treatment of mesh complications.⁷⁸

44. Underreporting of SMUS complications is also well-documented in the medical literature and discussed in the Nature article. Discrepancies exist between the SMUS complication rates reported by urologists from individual institutions, those reported in the literature, the (unreported) experience of tertiary care practices and those in the MAUDE (Manufacturer and User Facility Device Experience) database.⁷⁹ In our Nature review, we determined that approximately 88,000 removal surgeries should have been performed (based on published rates), and yet only a small fraction of such procedures are reported in the peer-reviewed literature.⁸⁰ Use of imperfect research methodologies, a lack of long-term follow up and reporting bias have been suggested as causes of these differences.⁸¹

45. Some authors and key opinion leaders have signed contracts with mesh manufacturers and have acted as paid consultants for mesh manufacturers. These contracts often contain language that prevents company consultants from reporting or discussing device complications without written company approval. In some articles, these conflicts are not disclosed.⁸²

46. The Prolene mesh in the TVT-S is laser cut in the manufacturing process, as opposed to being mechanically cut.⁸³ This means that the plastic mesh is cut into strips using a laser instead a cutting blade.⁸⁴ The result is that the mesh itself is stiffer than mechanically cut mesh. In fact, an internal memo from Becky Leibowitz to Paul Parisi and Dan Smith in late 2004 found that when the laser cut mesh was stretched it became about three times stiffer than the machine-cut TVT mesh.⁸⁵ Just four years later, in meeting notes, it is noted that there is a consensus that laser cut mesh is more rigid and stiff and that no clinical study has been done regarding the differences between laser cut mesh and mechanical cut mesh. The notes further indicate potential benefits of using mechanical cut mesh over laser cut mesh noting a lower rate of erosions, tensioning would

⁷⁶ E.g., Blaivas, 2015; ETH.MESH.00262089; ETH.MESH.00658508; ETH.MESH.03918253

⁷⁷ Brubaker L, et al. Missing data frequency and correlates in two randomized surgical trials for urinary incontinence in women. *Int Urogynecol J.* 2015; 26:1155-1159.

⁷⁸ Barski D and Deng DY. Management of mesh complications after SUI and POP repair: Review and analysis of the current literature. *Biomed Res Int.* 2015;2015:831285, p2. Doi: 10.1155/2015/831285. [Epub 2015 Apr 20].

⁷⁹ Blaivas 2015, 481-509, 484.

⁸⁰ Blaivas 2015, 481-509, 485.

⁸¹ Blaivas 2015, 481-509, 485.

⁸² E.g., ETH.MESH.00262089; ETH.MESH.08692936; ETH.MESH.02123291; ETH.MESH.08696084

⁸³ ETH.MESH.09951087; Deposition of Dan Smith, May 15, 2014, 48:11-17

⁸⁴ Lamont Dep. (9/11/13) 12:13-13:14

⁸⁵ ETH.MESH.01809080

be more similar to current products, and the edges of mechanical cut mesh might allow for an easier insertion.⁸⁶

47. Importantly, while these discussions about the differences between laser cut mesh and mechanical cut mesh were going on, most surgeons using the TVT products did not know what type of mesh they were using.⁸⁷ Thus, there is no way for doctors to adjust tensioning differently or be aware that the mesh is stiffer, or to warn patients of an increased risk of erosions. The difference in the stretch profile between mechanically cut and laser cut mesh also led Carl G. Nilsson and Christian Falconer, two of the inventors of the original TVT,⁸⁸ and Jean de Leval, the inventor of TVT-O, to refuse to use, and question the use, of laser cut mesh.⁸⁹

48. Additionally, the shorter length of the laser cut mesh in the TVT-S leads to more complications. A report titled “Things to consider as we assess next steps for a next generation sling,” includes a discussion regarding whether or not a shorter-length laser-cut mesh would be stiffer than even a longer laser-cut mesh.⁹⁰ Dan Smith notes that the shorter slings will not stretch as much as the full length slings (i.e., stiffer) giving rise to more complications and that doctors will have to tension this mesh differently.

49. Moreover, use of the laser cut mesh would make them unable to rely on the original studies and data they use to tout the safety and effectiveness of the original TVT.⁹¹ This data is something Ethicon wanted to rely on for this product.⁹² Additionally, laser cut mesh was never assessed on its own in a clinical trial.⁹³ Finally, the rigidity of the laser cut mesh can cause a higher incidence of erosion and sexual dysfunction than mechanically cut mesh.⁹⁴

50. It is well established in the medical and scientific literature that heavier weight, smaller pore sized mesh such as that used in the Gynecare TVT-S elicits a greater inflammatory and fibrotic reaction in women.⁹⁵

51. Despite moving to a lighter weight, larger pore sized mesh for its hernia products in the late 1990’s and for its pelvic organ prolapse products so as to minimize the body’s inflammatory and foreign body reaction to the polypropylene devices, Ethicon continued to manufacture the Gynecare TVT-S from the heavier weight, smaller pore sized mesh, ignoring the increased risks to patient safety and product efficacy.⁹⁶

⁸⁶ ETH.MESH.03916716

⁸⁷ ETH.MESH.09911296; ETH.MESH.09951087

⁸⁸ ETH.MESH.16416002, ETH.MESH.04048515

⁸⁹ ETH.MESH.03916716

⁹⁰ ETH.MESH.09911296

⁹¹ ETH.MESH.06040171; ETH.MESH.01706065

⁹² Trial Testimony of Katrin Elbert, *Perry v. Luu, et al.*, (2/11/15) 3328-30

⁹³ ETH.MESH.03941617

⁹⁴ ETH.MESH.00294195; ETH.MESH.03916716; ETH.MESH.01706065; ETH.MESH.03923121

⁹⁵ E.g., Klinge U, Junge K, Stumpf M, Ap AP, Klosterhalfen B. Functional and morphological evaluation of a lowweight, monofilament polypropylene mesh for hernia repair. *Journal of biomedical materials research*; 63(2):129-36; Klosterhalfen, 2005.

⁹⁶ E.g., ETH.MESH.07455220; ETH.MESH.09275875; ETH.MESH.02268619; ETH.MESH.02589032; ETH.MESH.01264260; Smith Dep. (2/3/2014) 723:9-724:6, 829:16-829:19; Burkley Dep. (5/22/13) 184:17-24

52. The Gynecare TVT-S should not have been designed for permanent implantation in the human body without proper animal and human studies because the polypropylene used therein can elicit a permanent and persistent inflammatory response⁹⁷ and can create dense scar tissue.⁹⁸ Ethicon internal documents confirm it was aware of problems contemporaneously.⁹⁹

53. The polypropylene mesh used in the Gynecare TVT-S creates scar plate that can entrap nerves, smooth muscle, and striated muscle and causes other tissue abnormalities.¹⁰⁰ Pore size, density, weight and surface area are all factors involved in scar plate formation.¹⁰¹ This increased scar plate formation has adverse clinical consequences in women, including distortion of the pelvic anatomy, chronic pain, dyspareunia and/or sexual impairment, bladder and/or bowel dysfunction and other complications. These forces can act on the entire structure of the Gynecare TVT-S.¹⁰²

54. The polypropylene mesh used in the Gynecare TVT-S shrinks unpredictably and asymmetrically, influenced by individual response, bacterial contamination, anatomical location, and time.¹⁰³ Because of and the unpredictable amount of shrinkage, it is not possible for the surgeon to determine the proper amount of tension to apply and there is no procedure that is really reliably “tension-free”. The consequences of mesh shrinkage are very significant, resulting in pain, dyspareunia, urinary symptoms, and other complications.

⁹⁷ E.g., Klinge, 1998 (Shrinking):965-9; Clave, A., Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants, *I Urogynecol J*, 2010 21:261-270; Klinge U, Klosterhalfen B, Muller M, Schumpelick V, “Foreign Body reaction to Meshes Used for the Repair of Abdominal Wall Hernias,” *Eur J Surg*, 1998 (164:951–960); Klosterhalfen, B, Junge, K, Klinge, U, “The lightweight and large porous mesh concept for hernia repair,” *Expert Rev. Med. Devices*, 2005 2(1); Binnebosel M, von Trotha K, Jansen P, Conze J, Neumann U, Junge K, “Biocompatibility of prosthetic meshes in abdominal surgery” *Semin Immunopathol*, 2011 (33:235-243).

⁹⁸ E.g., Heise, C. P., & Starling, J. R. (1998). Mesh inguinodynia: a new clinical syndrome after inguinal herniorrhaphy? *Journal Of The American College Of Surgeons*, 187(5), 514-518; Demirer, S., Kepenekci, I., Evirgen, O., Birsen, O., Tuzuner, A., Karahuseyinoglu, S., & Kuterdem, E. (2006). The effect of polypropylene mesh on ilioinguinal nerve in open mesh repair of groin hernia. *The Journal Of Surgical Research*, 131(2), 175-181; Klosterhalfen, 2005; Klinge, 1998 (Shrinking).

⁹⁹ E.g., Burkley Dep. (5/22/13) 184:17-24; ETH.MESH.05588123

¹⁰⁰ E.g., Heise, 1998; Demirer, 2006; Klosterhalfen, 2005; Vervest, H., Bongers, M. & van der Wurff, A. Nerve injury: an exceptional cause of pain after TVT. *Int. Urogynecol. J. Pelvic Floor Dysfunct.* 6, 665–667 (2006); Iakovlev V., M. G., Blaivas J. (2014). "Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh is Not Inert [Abstract]." *International Continence Society Meeting Annual Meeting*; ETH.MESH.01264260.

¹⁰¹ E.g., Iakovlev, 2014; ETH.MESH.01264260

¹⁰² E.g., Blaivas, J. G., et al. (2015). "Safety considerations for synthetic sling surgery." *Nat Rev Urol*

¹⁰³ E.g., Klinge, 1998 (Shrinking); Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. *Obstetrics and gynecology*. 2010;115(2 Pt 1):325-30; Mamy L, Letouzey V, Lavigne JP, Garric X, Gondry J, Mares P, et al. Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. *Int Urogynecol J*. 2011;22(1):47-52; Letouzey V, Huberlant S, Lavigne J, Mares P, Garric X, De Tayrac R. Is polypropylene mesh coated with antibiotics is efficient to prevent mesh infection and contraction in an animal infectious model? [Abstract]. 37th Annual Meeting of the International Urogynecological Association. 2012:193; Jacquetin B, Cosson M. Complications of vaginal mesh: our experience. *Int Urogynecol J Pelvic Floor Dysfunct.* 2009;20(8):893-6; Garcia-Urena MA, Vega Ruiz V, Godoy A, Baez Perea JM, Marin Gomez LM, Carnero Hernandez FM, et al. Differences in polypropylene shrinkage depending on mesh position in an experimental study. *Am J Surg*. 2007;193(4):538-42

55. In the Nature paper, we discussed the mechanisms for mesh-related complications. These include inflammatory reactions, fibrosis, deformation, nerve entrapment, degradation, shrinkage/contraction, migration, and stiffening. These material features of polypropylene mesh and their relationship to mesh complications are discussed in my expert report. Numerous recent peer-reviewed articles have confirmed the contribution of these properties into the mechanisms of mesh-related symptoms for patients.

56. Degradation was reported in papers by Iakovlev et. al and Imel et. al on the in vivo degradation of transvaginally implanted polypropylene products. Degradation progresses over time and results in clinically significant embrittlement, loss of flexibility mesh stiffening and deformation.^{104,105} Bendavid reported on the mechanism of hernia mesh repair pain. This new clinical syndrome, characterized by slow onset, relentless progression, and uncompromising lack of response to treatment, was attributed to nerve entrapment incased in dense scar tissue. According to the author, the pores of mesh need to be viewed as “mini-compartments” of biological tissue where the vasculature, nerves and their receptors are exposed to potential mechanical and chemical factors: scarring, entrapment, compression, tugging, deformation, contraction, hypoxia/acidosis, inflammation and edema.¹⁰⁶ In another study by Bendavid et. al, a marked increase in nerve density trapped in scar was observed in patients who had mesh-related pain, regardless of the surgical technique or surgical location.¹⁰⁷ Testing by Lee also discussed the mechanisms of chronic pain after MUS surgery, describing a “complex interplay of factors [that] can be causative, including synthetic material type, nerve and muscle injury, infection, contraction, erosion or extrusion.”¹⁰⁸

57. Questions have been raised in the peer-reviewed literature regarding the carcinogenic potential for transvaginally placed polypropylene mesh. We addressed this concern in our Nature review. These carcinogenic effects, leading to the development of sarcomas, have been studied in animal models. The basic research and clinical data suggest that implantation of polypropylene mesh might increase the risk of sarcoma. If a risk is present in humans, it is likely to be very low. Mutagenic effects, in general can take many years to accumulate and then a long period to cause a neoplasm. Detecting any oncogenic effects of SMUS implants would require a large cohort of patients with the same type of implant, and these patients would have to be followed up for a sufficiently long period of time, most likely at least 15 years.¹⁰⁹ However, a recent case of clear cell carcinoma associated with an eroded polypropylene sling was reported November, 2015 in the International Urogynecology Journal.¹¹⁰ A second case of squamous cell carcinoma associated with a midurethral sling was reported at the same time. In an accompanying editorial in the same

¹⁰⁴ Iakovlev VV, et al. Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients. 2015:00B:000-000, p10.

¹⁰⁵ Imel A, et al. In vivo oxidative degradation of polypropylene pelvic mesh. *Biomaterials*. 2015 Dec;73:131-41, 132.

¹⁰⁶ Bendavid R, et al. Mesh-related SIN syndrome. A surreptitious irreversible neuralgia and its morphologic background in the etiology of post-herniorrhaphy pain. *Int J Clin Med*. 2014; 5:799-810, 799.

¹⁰⁷ Bendavid R, et al. A mechanism of mesh-related post-herniorrhaphy neuralgia. *Hernia*. 2015 Nov 23, p6. [Epub ahead of print].

¹⁰⁸ Lee 2015, 205.

¹⁰⁹ Blaivas 2015, 481-509, 500.

¹¹⁰ Lin HZ, et al. A first reported case of clear cell carcinoma associated with delayed extrusion of midurethral tape. *Int Urogynecol J*. 2015 Nov 20. [Epub ahead of print].

journal issue, Goldman recognized that a cause-and-effect pattern could be concerning and recommended vigilance.¹¹¹ This is new information that supports my opinions that patients who receive mesh products should be monitored closely over a long-term period.

58. I have reviewed the Material Safety Data Sheet for the polypropylene used in the Gynecare TVT-S medical device and related documents. This document states in part, under INCOMPATIBILITY, that the following materials are incompatible with this product: Strong oxidizers such as chlorine, peroxides, chromates, nitric acid, perchlorates, concentrated oxygen, sodium hypochlorite, calcium hypochlorite and permanganates. Chlorine; Nitric acid.¹¹² The Gynecare TVT-S should not have been designed using this polypropylene because many of these chemicals are routinely found in human tissue.

59. The polypropylene mesh used in the Gynecare TVT-S degrades *in vivo*.¹¹³ Degradation has been reported to result in stiffening of the mesh and the presence of small molecular complexes and chemical products of degradation in surrounding tissues provides an additional stimulus for the chronic inflammatory response, which causes a continuous cycle of remodeling around the mesh filaments and extension of fibrosis.¹¹⁴ *In vivo* it has been well documented that mesh also stiffens.¹¹⁵ Dr. Iakovlev and I have recently published an abstract in a peer-review journal that describes mesh hardening, degradation, deformation, and nerve/muscle entrapment from a histological standpoint and how these findings relate to pain and other mesh complications.¹¹⁶

60. Ethicon's own internal document support my opinion that polypropylene mesh degrades in the body.¹¹⁷

All opinions are given to a reasonable degree of medical certainty. I reserve the right to amend or supplement this report if additional information becomes available. I also reserve the right to adopt all of my opinions in the other reports that I have submitted for the Wave 1 cases.

¹¹¹ Goldman HB and Dwyer. Polypropylene mesh slings and cancer: An incidental finding or association? Int Urogynecol J. 2015 Nov 19, p2. [Epub ahead of print].

¹¹² ETH.MESH.02026591.

¹¹³ E.g., Jongebloed WL, Worst JF. Degradation of polypropylene in the human eye: a SEM-study. Documenta ophthalmologica Advances in ophthalmology. 1986;64(1):143-52; Coda A, Bendavid R, Botto-Micca F, Bossotti M, Bona A. Structural alterations of prosthetic meshes in humans. Hernia : the journal of hernias and abdominal wall surgery. 2003;7(1):29-34; Costello CR, Bachman SL, Ramshaw BJ, Grant SA. Materials characterization of explanted polypropylene hernia meshes. Journal of biomedical materials research Part B, Applied biomaterials. 2007;83(1):44-9; Clave , 2010; Sternchuss G, Ostergard DR, Patel H. Post-Implantation Alterations of Polypropylene in the Human. J Urol. 2012;188(1):27-32

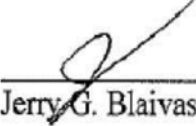
¹¹⁴ E.g., Iakovlev, 2014; Junge, 2001; Blaivas, 2015.

¹¹⁵ E.g., Costello, 2007 (Materials); Fayolle B, Audouin L, Verdu J. Oxidation induced embrittlement in polypropylene - a tensile testing study. Polymer Degradation and Stability. 2000;70(2000):333-40; Fayolle B, Audouin L, Verdu J. Initial steps and embrittlement in the thermal oxidation of stabilised polypropylene films. Polymer Degradation and Stability. 2002;75:123-9; Fayolle B, Audouin L, George GA, Verdu J. Macroscopic

¹¹⁶ Blaivas, 2015

¹¹⁷ ETH.MESH.07690752; DEPO.ETH.MESH.00004755; ETH.MESH.12831391; ETH.MESH.02589032; ETH.MESH.07192929; ETH.MESH.01264260; Burkley Dep., May 23, 2013 at 315:8-13.

This 1st day of February, 2016.



Jerry G. Blaivas, MD

III. FACTS OR DATA CONSIDERED IN FORMING OPINIONS

In addition to the references included herein, an Index is attached hereto and by reference made a part hereof. Please see **Exhibit “C”** attached.

IV. COMPENSATION

Dr. Blaivas’ Fee Schedule is attached hereto and by reference made a part hereof. Please see **Exhibit “B”** attached.

V. LISTING OF CASES IN WHICH TESTIMONY HAS BEEN GIVEN IN THE LAST FOUR YEARS

Merjem Delija v. Neil Sayegh, etc.; index no. 14449/2003

Jose Cuevas v. the Mount Sinai medical Center; Index no. 0017209/2004

Randy Smith, et al. v. Andrew Chan, M.D., et al.; Index No. 024786/2009

Katelyn Vercher, et al. v. Chiari Institute, et al.; 2:09-cv-01751-AKT

Lisa Marie Fontes, et al. v. American Medical Systems, Inc.; 2:12-CV-02472

Debbie Jilovec, et al., v. American Medical Systems, Inc.; 2:12-CV-05561

Joann Serrano, v. American Medical Systems, Inc.; 2:12-CV-3719

Mary Weiler, et al. v. American Medical Systems, Inc.; 2:12-CV-05836

Carolyn F. Smothers v. Boston Scientific Corp.; 2:12-cv-08016

Katherine L. Hall v. Boston Scientific Corp.; 2:12-cv-08186

Julia Wilson v. Boston Scientific Corp.; 2012-02626

Ronda Orozco, et al., v. Boston Scientific Corp.; 2012-03068

Maria Cardenas v. Boston Scientific Corp.; 2012-02912

Diane Albright v. Boston Scientific Corp.; 2012-00909

Jo Huskey, et. al v. Ethicon, Inc.; 2:12-cv-05201

Tonya Edwards, et. al v. Ethicon, Inc.; 2:12-cv-09972

Exhibit A

Curriculum Vitae

Name: Jerry G. Blaivas, MD

Office Address: 445 East 77th Street
New York, NY 10075
Tele: (212) 772 3900

Citizenship: United States of America

Licensure: New York #144945, January 1981

**Specialty
Certification:** American Board of Urology, 1978

Education: Tufts University School of Medicine M.D., 1968
Tufts College, B.A., 1964

Post Graduate:

Intern, General Surgery: Boston City Hospital
Boston, MA
1968 - 1969

Resident, General Surgery: Boston City Hospital
Boston, MA
1969 - 1971

Resident, Urology: Tufts-New England Medical Center
Boston, MA
1973 - 1976

Military: Major, United States Army Department of Orthopedics
(Active Duty) Walson Army Hospital
Fort Dix, NJ
1971-1973

**Faculty
Appointments:**

Adjunct Professor of Urology
SUNY Downstate Medical School
Brooklyn, NY
2008 - present

Clinical Professor of Urology

Blaivas

2

Weill Medical College of Cornell University
New York, NY
1993 - present

Professor of Clinical Urology
College of Physicians & Surgeons
Columbia University
New York, NY
1989 - 1993

Vice-Chairman, Department of Urology
College of Physicians & Surgeons
Columbia University
New York, NY
1987 - 1993

Director, Neurourology
College of Physicians & Surgeons
Columbia University
New York, NY
1981 - 1993

Associate Professor of Urology
College of Physicians & Surgeons
Columbia University
New York, NY
1981 - 1989

Associate Professor of Urology
Tufts University School of Medicine
Boston, MA.
1979 - 1981

Assistant Professor of Urology
Tufts University School of Medicine
Boston, MA.
1976 - 1979

Blaivas

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Hospital and University

Administrative Appointments:

Chief of Urogynecology
Attending Surgeon (Urology)
Lenox Hill Hospital
New York, NY
1999 - 2007

Attending Surgeon (Urology)
The New York Presbyterian Hospital
New York, NY
1993 - present

Attending Urologist
The Presbyterian Hospital
New York, NY
1992 - 1993

Director, Neurourology Laboratory
The Presbyterian Hospital
New York, NY
1981 - 1993

Associate Attending Urologist
The Presbyterian Hospital
New York, NY
1981 - 1992

Chief of Urology
Helen Hayes Hospital
West Havestraw, NY
1987 - 1993

Assistant Surgeon
New England Medical Center
Boston, Massachusetts
1976 - 1981

Director, Urodynamics Laboratory
New England Medical Center

Blaivas

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Boston, MA
1976 - 1981

Consultant in Urology
Massachusetts Rehabilitation Hospital
Boston, MA 1977 - 1981

Consultant in Urology
Braintree Hospital
Braintree, MA 1977 - 1981

Attending Physician, Surgical Service
Boston Veterans Administration Medical Center
Boston, MA
1977 – 1981

**Professional
Societies:**

American Association of Genitourinary Surgeons
American Board of Urology
American College of Surgeons
American Urogynecologic Society
American Urologic Society, New York Section
American Urological Association
Chilean Urologic Society, Honorary Member
International Continence Society
Massachusetts Medical Society (1973 - 1981)
National Board of Medical Examiners
New York Academy of Medicine
Societe Internationale d'urologie
Society for Urodynamics and Female Urology
Society of Pelvic Surgeons
Society of University Urologists

**Honors and
Awards:**

Victor A. Politano Award, American Urological Association, 2009

Jerry G. Blaivas Honorary Lectureship, Society of Urodynamics and Female Urology,
established 2007

Continence Care Champion, National Association For Continence, 2005

Blaivas

5

Pfizer-American Urological Association Visiting Professor Award, 2004

The Best Clinical Study for the Year 2000.
Society for Urodynamics and Female Urology, 2000

Lifetime Achievement Award
Society for Urodynamics and Female Urology, 1999

Brantley Scott M.D. Award.
American Foundation for Urologic Disease, 1999.

J. Marion Sims Award
American Uro-Gynecologic Society, 1993

Best Doctors in America, 1992-present

Best Doctors in New York, 1992-present

Zimskind/Kendall Award
Urodynamic Society, 1985

First Prize for Research
Annual Meeting of the International
Continence Society, Leiden, 1982

Winner, Team Debate
Joint Meeting of the International
Continence Society and the Urodynamic
Society, Los Angeles, 1980

Commendations Medal
United States Army, 1973

Sword and Shield Honor Society
Tufts College, 1965

Hospital and University

Committees: Executive Committee
Department of Urology
College of Physicians & Surgeons
Columbia University, 1981-1993

Blaivas

6

Chairman, Quality Assurance Committee
Department of Urology
Columbia Presbyterian Medical Center
1986 - 1991

Committee on Computer Development for Medical
Applications, The Presbyterian Hospital
1985 - 1993

Medical Evaluation Committee
Columbia Presbyterian Medical Center
1985 - 1987

Human Investigation Committee
Department of Urology
Columbia Presbyterian Medical Center
1981 - 1993

Chairman, Patient Care Committee
The Presbyterian Hospital
1981 - 1986

Executive Committee
Tufts University School of Medicine
1978 - 1981

Doctor's Office Committee
Columbia-Presbyterian Medical Center
1988 - 1993

**Professional
Committees:**

Executive Committee
Society for Urodynamics and Female Urology
1999-present

Chairman, Voiding Dysfunction Committee
American Urological Association
1996-2000

Advisory Board Member

Blaivas

7

New York Menopause Center
1996 - 2000

Bladder Health Council
American Foundation for Urologic Diseases
1996 - present

Guidelines Panel on Surgical Treatments for Female Urinary Incontinence American
Urological Association
1994 - Present

Executive Committee
Urodynamics Society
1993-1999

Chairman New Technology Council
American Urological Association
1993 - 1997

Guest Examiner
American Board of Urology
1992 - 1996

President
Urodynamic Society
1992 - 1993

Member, BPH Guidelines Panel
Agency for Health Care & Policy Review
1989 - 1996

Technical Advisor
Incontinence Guideline Panel
Agency for Health Care & Policy Review
1989 - 1996

Practice Parameters & Guidelines Committee
American Urological Association
1991 - 1998

Member, Terminology Committee

Blaivas

8

American Urological Association
1991 - 1993

Chairman, Biomedical Engineering Committee
American Urological Association
1990 - 1993

Vice-Chairman, New Technology Committee
American Urological Association
1990 - 1993

Vice President
Urodynamic Society
1989 - 1991

Examination Committee
American Board of Urology
American Urological Association
1989 - 1993

Protocol Committee
Measurement Committee
AUA Cooperative BPH Study
1989 - 1993

Member, ad hoc Committee on Female Urology
American Urological Association
1988 - 1993

Advisory Board, Continence Program for Women
University of Virginia
1988 - 1996

Program Committee, Annual Meeting of the
American Urological Association
1988 - 1995

Patient Management Technology Committee
National Multiple Sclerosis Foundation
1987 - 1991

Blaivas

9

Secretary, Urodynamic Society
1986 - 1989

National Metric Council - Representative from the
American Urological Association
1986 - 1991

Chairman, Urology Sub-Committee
American Society for Testing and Materials
1986 - 1991

Co-Chairman, Annual Urodynamic Society Meeting
1985

Program Committee, Combined Meeting of the
International Continence Society and the
Urodynamic Society
1985

Vice-Chairman, Urology Sub-Committee
American Society for Testing and Materials
1985 - 1986

Program Committee, Annual Meeting of the
American Urological Association
1984 - 1986

Standardization Committee
International Continence Society
1983 - 1991

Medical Advisory Board, New York Chapter
National Multiple Sclerosis Foundation
1983 - 1991

Member-at-large
Executive Committee, Urodynamic Society
1982 - 1984

Program Chairman
Annual Urodynamic Society Meeting, Boston

1981

Chairman, Nomenclature Committee
Urodynamic Society
1980 -1985

Education Committee
National Multiple Sclerosis Foundation
1980 - 1990

Neurophysiology Committee
Urodynamic Society
1980 - 1986

Program Committee, Combined Meeting of the
International Continence Society and the
Urodynamic Society
1980

Biomedical Engineering Committee
American Urological Association
1980 - 1993

Chairman, Task force on Urodynamic Procedures
Urodynamic Society
1980 – 1984

Editorial Positions: Editor-in-Chief, Neurourology and Urodynamics
1981 - 2007

Editorial Boards: Neurourology & Urodynamics 1981 - present
 Contemporary Urology 1998 - 2007
 International Urogynecology Journal 2002 - present

Reviewer: British Journal of Urology
International Urogynecology Journal
Journal of Urology
Urology
Obstetrics & Gynecology
The New England Journal of Medicine
American Journal of Physiology

Blaivas

11

Brain
Neurology

Consulting Committee: Urologia Integrada y de Investigacion

Previous Grant Support:

Smith Kline Beecham 1993 - 1995	Effects of once daily dosing with two dose levels of epristeride or placebo on the voiding detrusor pressure in patients with bladder outflow obstruction due to benign prostatic hyperplasia.
Eli Lilly 1993 - 1995	Duloxetine vs. placebo in patients with urinary incontinence - assessment of subjective & objective parameters. \$92,500
American Foundations Of Urologic Diseases Scholar Award (Faculty Sponsor) 1988 - 1990	Parameters of Detrusor Contractility \$50,000
National Multiple Sclerosis Society 1977 - 1978	The Diagnosis, Treatment and National History of Voiding Disturbances in Multiple Sclerosis Grant # RG1108-A-1 \$78,418
National Multiple Sclerosis Society 1978 - 1980	The diagnosis, treatment and national history of voiding disturbances in multiple sclerosis. Grant # RT1108-B-2 \$113,915
Merrell Research Center 1978	Effect of Oral Candicidin on on Benign Prostatic Hypertrophy, \$52,000
Smith, Klein & French 1982	Dose Range Study of Phenoxybenzamine in Benign

Blaivas

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Prostatic Hypertrophy
\$27,000

Eastern Paralyzed
Veterans
1983 - 1984
Grant \$100,000

NeuroUrology Fellowship

Eastern Paralyzed
Veterans
1984 - 1985
Training Grant \$17,000

Neurourology Nurse

Roerig
Pharmaceuticals
1984 - 1985

Geocillin in the Treatment of
Recurrent Urinary Tract Infections
Study # 83-R-003
\$25,000

Roerig
Pharmaceuticals
1985-1986

Geocillin for the Treatment of
Bacterial Prostatitis in Patients with Multiple
Sclerosis or Spinal Cord Injuries with Associated
Dysfunctional Urinary Bladders
Study # 84-R-014
\$18,000

American Federation
For Aging (AFAR)
1987 - 1988

Urodynamics of Aging
AFAR CU50384501
\$16,000

Embassy Arab
Republic of Egypt
Cultural and Educational
Bureau Peace Fellowship
Program

Bladder Outlet Obstruction
PF # 2436 - \$17,000

Spinal Cord Research Parameters of Bladder
Foundation
1989 – 1990

Contractility in an In-vitro
Rabbit Bladder Model, \$19,200

National Multiple
1988 - 1991

Neurourodynamic Evaluation Sclerosis Foundation of Multiple Sclerosis
Grant # RG1997-A-4

Blaivas

13

\$116,682

PUBLICATIONS**Articles in Peer Review Journals:**

1. **Blaivas JG**, Pais, VM, Spellman, RM. Chemolysis of Residual Stone Fragments After Extensive Surgery for Staghorn Calculi. *Urology* 6:680-6, 1975.
2. **Blaivas JG**, Pais VM, Retik AB. Paraurethral Cysts in the Female Neonate. *Urology* 7:504-7, 1976.
3. **Blaivas JG**, Previte SR, Pais VM. Idiopathic Pelviureteric Varices. *Urology* 9:207-1, 1977.
4. **Blaivas JG**, Labib KB, Bauer SB, Retik AB. A New Approach to Electromyography of the External Urethral Sphincter. *J Urol* 117:773-7, 1977.
5. **Blaivas JG**, Labib KB, Bauer SB, Retik AB. Changing Concepts in the Urodynamic Evaluation of Children. *J Urol* 117:778-3, 1977.
6. **Blaivas JG**, Labib, KB. Urinary Retention in the Female: Complete Urodynamic Evaluation. *Urology* 10:383, 1977.
7. Rao CN, **Blaivas JG**. Primary Renal Artery Dissecting Aneurysms, A review. *J Urol* 118:716-9, 1977.
8. Labib KB, Bauer SB, **Blaivas JG**. External Sphincter Electromyography in a Comprehensive Urodynamic Evaluation. *Archives Phys Med & Rehab*, 58:521, 1977.
9. **Blaivas JG**, Labib KB, Scott RM. Urodynamic Evaluation as neurologic test of Sacral Cord Function. *Urology* 9:682, 1979.
10. **Blaivas JG**, Bhimani G, Labib KB. Vesicourethral Dysfunction in Multiple Sclerosis. *J Urol* 122:342-7, 1979.
11. **Blaivas JG**, Labib KB, Michalik SJ, Zayed AAH. Failure of Bethanechol Denervation Supersensitivity as a Diagnostic Aid. *J Urol* 123:199, 1980.
12. **Blaivas JG**, Labib KB, Michalik SJ, Zayed AAH. Cystometric Response to Propanetheline in Detrusor Hyperreflexia: Therapeutic Implications. *J Urol* 124:259, 1980.
13. **Blaivas JG**. Management of Bladder Dysfunction in Multiple Sclerosis. *Neurology* 30(2):12, 1980.

14. **Blaivas JG**, O'Donnell TF, Gottlieb P, Labib KB. Comprehensive Laboratory Evaluation of Erectile Dysfunction. *J Urol* 124:201,1980.
15. **Blaivas JG**, Sinha HPM, Zayed AAH, Labib KB. Detrusor External Sphincter Dyssynergia, *J Urol* 125:542-4,1981.
16. **Blaivas JG**, Sinha HPM, Zayed AAH, Labib KB. Detrusor External Sphincter Dyssynergia: A detailed EMG study. *J Urol* 125:545-8,1981.
17. **Blaivas JG**, Fisher DM. Combined Radiographic and Urodynamic Monitoring: Advances in Technique. *J Urol* 125:693-4,1981.
18. **Blaivas JG**, Zayed AAH, Labib KB. The Bulbocavernosus Reflex in *Urology*: A Prospective Study of 299 Patients. *J Urol* 126:197-9,1981.
19. **Blaivas JG**. The Neurophysiology of Micturition. *J Urol* 127:958-3,1982.
20. **Blaivas JG**, Awad SA, Bissada N, Khanna OP, Krane RJ, Wein AJ, et al. Urodynamic Procedures: Recommendations of the Urodynamic Society. 1. Procedures Which Should be Available for Routine Urologic Practice. *Neurourol Urodyn* 1:51-5,1982.
21. Sant GR, Heaney JA, Parkhurst EC, **Blaivas JG**. Obstructive Uropathy. A Potentially Serious Complication of Reconstructive Vascular Surgery. *J Urol* 129:16-2,1982.
22. Barbalias GA, **Blaivas JG**. Neurourologic Implications of the Pathologically Open Bladder Neck. *J Urol* 129:780-3,1983.
23. Zinner NR, Susset J, Coolseat BRLA, Griffiths D, Jonas U, Sterling AM, **Blaivas JG**, et al. Great Debate Resolved: The Urethral Closure Pressure Profile Should be Used For Diagnosis and Management of Female Stress Incontinence. *Neurourol Urodyn* 2:81-99,1983.
24. **Blaivas JG**, Barbalias GA. Characteristics of Neural Injury After Abdominal Perineal Resection. *J Urol* 129:84-7,1983.
25. Sant G, **Blaivas JG**, Meares EM. Hemiacidrin Irrigation in the Management of Struvite Calculi: Long Term Results. *J Urol* 130:1048-50,1983.
26. Norlen LJ, **Blaivas JG**, Gable H. Cystopathy in Patients With Severe Diabetic Nephropathy. Diabetic Nephropathy,1983.

27. **Blaivas JG.** Sphincter Electromyography. *Neurourol Urodyn* 2:269-88,1983.
28. Katz GP, **Blaivas JG.** A Diagnostic Dilemma: When Urodynamic Findings Differ From the Clinical Impression. *J Urol* 129:1170-4,1983.
29. Norlen LJ, **Blaivas JG**, Grodin W, Lundberg JM. Contractile Effect of Substance P on the Canine Urinary Bladder In Vivo. *Neurourol Urodyn*, 2:323-7,1983.
30. **Blaivas JG**, Barbalias GA. Detrusor External Sphincter Dyssynergia in Men With Multiple Sclerosis: An Ominous Urological Condition. *J Urol* 131:91-4,1984.
31. Barbalias GA, **Blaivas JG**, Klauber G. Critical Evaluation of the Crede Maneuver: A Urodynamic Study of 207 Patients. *J Urol* 131:91-4,1984.
32. **Blaivas JG.** Multichannel Urodynamic Studies. *Urology* 23:421-38,1984.
33. Sawczuk I, **Blaivas JG.** Successful Surgical Treatment of Giggle Incontinence. *Neurourol Urodyn* 3:63,1984.
34. **Blaivas JG.** Urodynamic Diagnosis of Primary Bladder Neck Obstruction. *World J Urol* 2:191,1984.
35. Oliver LM, **Blaivas JG**, McGuire E, Susset, J. Functional Vaginal Electrical Stimulation (FVES) for the Treatment of Frequency and Incontinence in Women. Proceedings of the Urodynamic Society, p47,1984.
36. **Blaivas JG**, Salinas J. Type III Stress Urinary Incontinence: The Importance of Proper Diagnosis and Treatment. *Surgical Forum* 35:472,1984.
37. **Blaivas JG.** Salinas J., Katz P. Role of Urodynamic Testing in the Evaluation of Subtle Neurourological Lesions. *Neurourol Urodyn* 4:211-8,1985.
38. Abrams P, **Blaivas JG**, Stanton SL, Andersen J, Fowler CJ, Gerstenberg T, et al. Sixth Report on the Standardisation of Terminology of Lower Urinary Tract Function. Procedures Related to Neurophysiological Investigations: Electromyography, Nerve Conduction Studies, Reflex Latencies, Evoked Potentials and Sensory Testing. The International Continence Society on Standardisation of Terminology, New York, *Scand J Urol Nephrol* 20:161-4,1986
39. Norlen L, **Blaivas JG.** Unsuspected Proximal Urethral Obstruction. *J Urol* 135:972-6,1986.
40. Salinas J, Berger Y, De La Rocha RE, **Blaivas JG.** Urologic Evaluation in the Shy- Drager Syndrome. *J Urol* 135:741-3,1986.

41. Abrams P, Andersen JT, **Blaivas JG**, Stanton SS. Sixth Report of the Standardization of Terminology of Lower Urinary Tract Function: Procedures Related to Neurophysiologic Investigations. *Neurourol Urodyn* 5:373-9,1986.
42. Axelrod SA, **Blaivas JG**. The Distinction Between Poor Detrusor Contractility and Bladder Outlet Obstruction. Proceedings of the International Continence Society. Boston, 1986.
43. Axelrod SA, **Blaivas JG**. Bladder Neck Obstruction in Women. *J Urol* 137:497-9,1987.
44. BergerY, **Blaivas JG**, De La Rocha RE, Salinas JM. Urodynamic Findings in Parkinson's Disease. *J Urol* 138:836-8,1987.
45. Abrams P, **Blaivas JG**, Stanton SL, Andersen J, Fowler CJ, Gerstenberg T, Murray K. Sixth Report on the Standardization of Terminology of Lower Urinary Tract Function. Procedures Related to Neurophysiological Investigations: Electromyography, Nerve Conduction Studies, Reflex Latencies, Evoked Potentials and Sensory Testing. The International Continence Society, *Br J Urol* 59:300-4,1987.
46. **Blaivas JG**, Olsson CA. Stress Incontinence: Classification and Surgical Approach. *J Urol* 139:727-1,1988.
47. Sarky MS, **Blaivas JG**. Functional Types of Prostatic Obstruction. *Neurourol Urodyn* 7:221-2,1988.
48. Sarky MS, **Blaivas JG**. Low-Pressure Low-Flow Syndromes. A Computer Based Classification on Functional Basis. *Neurourol Urodyn* 7:225-6,1988.
49. Sarky MS, **Blaivas JG**, Schussler G. Bladder Outlet Conductance: Evolution, Normal and Obstructive Patterns. *Neurourol Urodyn* 7:223-4,1988.
50. **Blaivas JG**. Pathophysiology and Differential Diagnosis of Benign Prostatic Hypertrophy. *Urology* 32:supp5-11,1988.
51. Abrams P, **Blaivas JG**, Stanton SL. Andersen JT. The Standardisation of Terminology of Lower Urinary Tract Function. *Neurourol Urodyn* 7:403-26,1988.
52. Kaplan SA, **Blaivas JG**. Diabetic Cystopathy. *J Diabet Complic* 2:133-9,1988.
53. **Blaivas JG**. Vaginal Flap Urethral Reconstruction: An Alternative to Bladder Flap Neourethra. *J Urol* 141:542-5,1989.

54. Kaplan SA, Brown WC, **Blaivas JG**. Parameters of Detrusor Contractility: Effects of Hysteresis and Bladder Volume in an In-Vitro Whole Rabbit Model. *Surgical Forum*, Volume XL 665-6,1989.
55. Kaplan SA, **Blaivas JG**, Brown WC, Schuessler G. Parameters of Detrusor Contractility: The Effect of Bladder Volume and Outlet Resistance on Qmax, Power and Work in In-Vitro Whole Rabbit Model. *Neurourol Urodyn* 8:375-6, 1989.
56. **Blaivas JG**. Diagnostic Evaluation of Urinary Incontinence. *Urology* 36:4,1990.
57. BergerY, Salinas JN, **Blaivas JG**. Urodynamic Differentiation of Parkinson's Disease and the Shy Drager Syndrome. *Neurourol Urodyn* 9:117-1,1990.
58. BergerY, **Blaivas JG**, Oliver L. Urinary Dysfunction in Transverse Myelitis. *J Urol* 144:103-5,1990.
59. **Blaivas JG**. Surgical Treatment of Urinary Incontinence in 223 Consecutive Women. *Neurourol Urodyn* 9:401-2,1990.
60. Chancellor MB, Otter MW, Kaplan SA, **Blaivas JG**. A New Method of Measuring Uroflow in the Rat Bladder. *Neurourol Urodyn* 9:391-2,1990.
61. **Blaivas JG**. Diagnostic Evaluation of Incontinence in Patients with Neurourologic Disease, *J Am Geriatr Soc* 38:306-0,1990.
62. Kaplan SA, **Blaivas JG**, Brown WC, Levin RM. Parameters of Detrusor Contractility: The Effect of Hysteresis, Electrical Stimulation and Bladder Volume in an In-Vitro Whole Rabbit Model. *Neurourol Urodyn* 10:53-9,1991.
63. **Blaivas JG**. Diagnostic Evaluation of Incontinence. *Urology* 36:supp11-20,1991.
64. Chancellor MB, **Blaivas JG**, Axelrod S, Kaplan SA. Bladder Outlet Obstruction Versus Impaired Detrusor Contractility: The Role of Uroflow. *J Urol* 145:810-2,1991.
65. Luangkhot R, Peng B, and **Blaivas JG**. Ileocecocolostomy for the Management of Refractory Neurogenic Bladder: Surgical Technique and Urodynamic Findings. *J Urol* 146:1340-4,1991.
66. **Blaivas JG**, Jacobs BZ. Pubovaginal Sling for the Treatment of Complicated Stress Incontinence. *J Urol* 145:1214-8,1991.
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Books

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2. Problems in Urology: Neurourology and Its Role in Urologic Disease: Part I, **Blaivas JG**, Chancellor MB, Guest Editors, Paulson Editor-in-Chief. 6:4,1992.
3. *Practical Neurourology: Genitourinary Complications in Neurourologic Disease*, Edited by **Blaivas JG**, Chancellor MB. Butterworth-Heineman, Boston, 1995.
4. *Topics in Clinical Urology: Evaluation and Treatment of Urinary Incontinence*, Edited by **Blaivas JG**. Igaku-Shoin. New York,1996.
5. **Blaivas JG**, Chancellor MB (eds.). *Atlas of Urodynamics*, Williams and Wilkins, 1996.
6. **Blaivas JG**. *Conquering Bladder and Prostate Problems: an Authoritative Guide for Men and Women*, Plenum Publishing Corp. New York, 1998.
7. **Blaivas JG**, Lepor H, Nitti VW, Weiss JP. *Case Studies in Benign Prostatic Hyperplasia*, Isis Medical Media Ltd. 2000.
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12. Weiss, JP, **Blaivas, JG**, van Kerrebroeck, PEV, Wein, AJ, *Nocturia: Causes, Consequences and*

Clinical Approaches, Springer, New York, 2012

VISITING PROFESSOR AND NAMED LECTURESHIPS

1. Universitas Complutensas (Madrid)
2. Scandinavian Association of Urology, 1984
3. Sociedad Chilena de Urologia, 1985
4. University of Washington
5. University of Texas (Dallas), 1990
6. Tufts University, Kamil B. Labib Memorial Lecture
7. University of Iowa
8. University of Pennsylvania, 2000
9. University of Massachusetts, Harold M. Lieberman Memorial Lecture
10. Loyola University, Roland R. Cross Visiting Professor of Urology, 1992
11. Northeastern Section of the American Urologic Section, George F. Slotkin Lectureship, 2000
12. Beth Israel Medical Center (New York)
13. Case Western Reserve University, 2001
14. University of Alabama
15. Mayo Clinic (Jacksonville)
16. Albany Medical College, 2001
17. University of Toronto, 2003
18. Canadian Urologic Association
19. University of Cincinnati, 2004
20. University of Massachusetts, 2004

21. University of Buffalo, 2004.
22. Hugh Hampton Young lecture, Mid-Atlantic Section, AUA, 2005
23. University of Vermont 2012

Jerry G. Blaivas, MD, FACS
Biographical Sketch

Dr. Blaivas is an internationally renowned urologist with over thirty years of clinical experience. He is, as well, an acclaimed academician, educator, writer and editor with an unimpeachable reputation for honesty and compassion. His clinical expertise ranges from office urology to the most complicated and difficult surgical problems. Known as a “doctor’s doctor,” he is considered the “doctor of last resort” by patients and doctors alike when they experience multiple failed treatments.

Dr. Blaivas is Clinical Professor of Urology at Weill Cornell Medical College, Adjunct Professor at SUNY Downstate and Attending Surgeon at New York Presbyterian Hospital and Lenox Hill Hospital. He is former Professor of Urology and Vice Chairman of the Department of Urology at Columbia University College of Physicians and Surgeons.

In addition to a widely acclaimed expertise in routine urologic conditions such as prostate problems in men, pelvic organ prolapse (dropped bladder) in women and incontinence in both sexes, Dr. Blaivas was one of the originators of urodynamics and pioneered many of the current surgical procedures to correct stress incontinence, urinary fistulas, urethral diverticulum, overactive bladder and neurogenic bladder. He is one of the few surgeons who routinely performs reconstructive surgery for prolapse and incontinence without the use of mesh and has published one of the largest series in the world on treatment of mesh complications. He has a particular interest and expertise in complex urologic problems – complications of radiation and prostate surgery, failed incontinence surgery and failed prolapse surgery.

Dr. Blaivas is former President of the Urodynamics Society and the recipient of numerous awards, including the Lifetime Achievement Award from the Society for Urodynamics and Female Urology, the Victor A. Politano Award from the American Urological Association, the F. Brantley Scott M.D. Award from the American Foundation for Urologic Disease, the J. Marion Sims Award from the American Uro-Gynecologic Society and the Paul Zimskind Award from the Urodynamic Society.

In addition, Dr. Blaivas has consistently been listed in *New York Magazine’s Best Doctors* and *Castle Connolly’s America’s Top Doctors* and *Top Doctors: New York Metro Area* from the publications’ inception in 1992 to the present.

Dr. Blaivas is the Founder of the major scientific journal *Neurourology & Urodynamics* and was Editor-in-Chief from 1982-2006. He is on the editorial board of *Contemporary Urology* and *International Urogynecology Journal* and is a reviewer for a number of other journals, including the *Journal of Urology*, *Urology*, *The New England Journal of Medicine*, and *British Journal of Urology*. He is the primary author of over 400 peer review scientific articles, book chapters and reviews and has edited seven books. He is a member of numerous professional societies, including the American Association of Genitourinary Surgeons, Society of Pelvic Surgeons, American Urological Association, American College of Surgeons, Society for Urodynamics and Female Urology, American Urogynecologic Society, and the International Continence Society.

Dr. Blaivas founded the not-for-profit organization, the Institute for Bladder and Prostate Research, which is dedicated to research relating to the lower urinary tract and female genital tract, including urinary incontinence, prostate conditions, neurogenic bladder, interstitial cystitis and genital prolapse. In addition, he is the author of a book for the lay public on bladder and prostate conditions entitled, *Conquering Bladder and Prostate Problems; an Authoritative Guide for Men and Women*.

Exhibit B

Jerry G. Blaivas, MD, FACS

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445 East 77th Street
New York, NY 10075

Diplomat
American Board of Urology

Phone (212) 772-3900
Fax (212) 772-1919

November 1, 2012

Margaret M. Thompson, MD JD MPAFF
Mueller Law
404 W. 7th Street
Austin, TX 78701

Re: Dr. Blaivas' fee schedule

To whom it may concern:

Per your request, I have set forth Dr. Blaivas' fee schedule below. Please be advised that **fees are required prior to or at the time of service.**

\$750 per hour for review of medical records and preparation of reports.

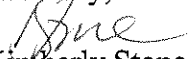
\$7,500 for a half day of deposition testimony, trial testimony and/or consultations with attorney, (including travel time)

\$15,000 for a full day of deposition testimony, trial testimony and/or consultations with attorney, (including travel time)

Given the nature of Dr. Blaivas' practice, he must be notified well in advance of any cancellation. Otherwise the above fee schedule will apply.

Please confirm your agreement to the above terms by signing below.

Sincerely,


Kimberly Stone

Addressee ***Sign***

Addressee ***Print***

Exhibit C

Document Date	Title	Primary Author	Publication
2013-00-00	Correction: Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse		N ENGL J MED 368;4:394
2012-00-00	GUIDE TO LEARNING IN FEMALE PELVIC MEDICINE AND RECONSTRUCTIVE SURGERY		
	Evaluation and Management of Complications From Synthetic Mesh After Pelvic Reconstructive Surgery: A Multi-Center Study	Abbot, et al	Presentation Number: Paper 29
2014-01-01	Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study	Abbott, et al	Am J Obstet Gynecol 2014;210:163.e1-8
2011-01-01	Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: A Meta-Analysis of Effectiveness and Complications	Abdel-Fattah, et al	European Urology 60 (2011) 468 - 480
2006-01-01	How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure	Abdel-Fattah, et al	BJU Int, 98(3), 594-598
2008-01-01	Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapse	Abdel-Fattah, et al	BJOG 2008;115:22–30
	A RANDOMISED PROSPECTIVE SINGLE-BLINDED STUDY COMPARING "INSIDE-OUT" VERSUS "OUTSIDE-IN" TRANSOBTURATOR TAPES IN THE MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE (E-TOT STUDY); 3 YEARS FOLLOW-UP.	Abdel-fattah, et al	Poster 18
2010-01-01	Evaluation of transobturator tapes (E-TOT) study: randomised prospective single-blinded study comparing inside-out vs. outside-in transobturator tapes in management of urodynamic stress incontinence: Short term outcomes	Abdel-fattah, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 149 (2010) 106-111
2010-04-12	Randomised prospective single-blinded study comparing 'inside-out' versus 'outside-in' transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study	Abdel-fattah, et al	BJOG 2010;117:870—878

2010-05-18	Tension-Free Vaginal Tape versus Secure Tension-Free Vaginal Tape in Treatment of Female Stress Urinary Incontinence	Abdelwahab, et al	Current Urology, 4(2), 93-98
2011-01-01	Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials; a systematic review	Abed, et al	Int Urogynecol J (2011) 22:789–798
2011-01-01	Treatment of moderate to severe female stress urinary incontinence with the adjustable continence therapy (ACT) device after failed surgical repair	Aboseif, et al	World J Urol (2011) 29:249–253
2011-00-00	Is Tissue Engineering and Biomaterials the Future for Lower Urinary Tract Dysfunction (LUTD)/Pelvic Organ Prolapse (POP)?	Aboushwareb, et al	Neurourology and Urodynamics 30:775--782 (2011j)
2009-01-01	Tissue mechanics, animal models, and pelvic organ prolapse: A review	Abramowitch, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 144S (2009) S146–S158
2011-01-01	Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe	Abrams, et al	European Urology 60:1207-1211
2006-12-01	ACOG Committee Opinion Number 352: Innovative Practice: Ethical Guidelines	ACOG	ACOG Committee Opinion No. 352
2007-02-01	ACOG PRACTICE BULLETIN NUMBER 79: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN-GYNECOLOGISTS	ACOG	The American College of Obstetrics & Gynecology
2007-09-01	ACOG PRACTICE BULLETIN NUMBER 85: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN - GYNECOLOGISTS NUMBER 85	ACOG	The American College of Obstetricians and Gynecologists
2005-06-01	ACOG Practice Bulletin Number 63: Clinical Management Guidelines for Obstetrician-Gynecologists	Acog Committee on Practice Bulletins--Gynecology	Obstet Gynecol
2008-10-01	A Randomized Comparison of Two Synthetic Mid-Urethral Tension-Free Slings	Agarwala N	UroToday International Journal / Vol 1 / Iss 4/
2007-01-01	Laparoscopic sacral colpopexy with Gynemesh as graft material-Experience and results	Agarwala, et al	Journal of Minimally Invasive Gynecology (2007) 14, 577–583

2014-01-01	Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence	Agnew, et al	Int Urogynecol J (2014) 25:235–239
2006-00-00	Mesh migration following repair of inguinal hernia: a case report and review of literature	Agrawal, Avill	Hernia (2006) 10: 79--82
2011-01-01	Long term patient satisfaction after suburethral sling operation for stress incontinence	Al-Omary, Atalla	Int Urogynecol J (2011) 22 (Suppl 3):
2007-01-01	Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence	Albo, et al	N Engl J Med 2007;356:2143-55
2012-12-01	Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24 Months	Albo, et al	J Urol Vol. 188, 2281-2287
2009-00-00	Isolation of fibroblasts for coating of meshes for reconstructive surgery: differences between mesh types	Albrich, et al	Regenerative Medicine
2003-01-02	Use of Cadaveric Fascia Lata To Correct Grade IV Cystocele	Almeida,et al	International Braz J Urol Vol. 29 (1): 48-52
2011-01-01	Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse	Altman, et al	N Engl J Med 2011;364:1826-36
2007-02-01	Perioperative Morbidity Using Transvaginal Mesh in Pelvic Organ Prolapse Repair	Altman, et al	Obstet Gynecol 2007;109:303–8
	INTRA- AND PERIOPERATIVE MORBIDITY FOLLOWING PELVIC ORGAN PROLAPSE REPAIR USING A TRANSVAGINAL SUTURE CAPTURING MESH DEVICE COMPARED TO TROCAR GUIDED TRANSVAGINAL MESH AND TRADITIONAL COLPORRAPHY	Altman, et al	Abstract
2007-01-01	Lower urinary tract injuries associated with the out-in transobturator tape - is cystoscopy required An Argentinean multicenter experience	Altuna,et al	Int Urogynecol J (2007) 18 (Suppl 1):
2009-01-01	Clinical and Quality-of-Life Outcomes after Autologous Fascial Sling and Tension-Free Vaginal Tape: A Prospective Randomized Trial	Amaro, et al	International Braz J Urol Vol. 35 (1):60-67
1997-01-01	Classification of biomaterials and their related complications in abdominal wall hernia surgery	Amid PK	Hernia (1997) 1:15-21

2010-01-01	Complications of polypropylene mesh in prolapse surgery	Ammembal, Radley	OBSTETRICS, GYNAECOLOGY AND REPRODUCTIVE MEDICINE 20:12, 359-364
1998-01-01	Concise review of mechanisms of bacterial adhesion to biomaterial surfaces	An, Friedman	J Biomed Mater Res (Appl Biomater) 43: 338—348
2008-01-01	Foreign Body Reaction to Biomaterials	Anderson, et al	SEMIN. IMMUNOL. 20(2): 86-100
1985-01-01	Utilization of Adipose Tissue Biopsy in Characterizing Human Halogenated Hydrocarbon Exposure	Anderson, HA	Environmental Health Perspectives
2007-01-01	Prospective Clinical Trial Comparing Obtape and DUPS to TVT: One-Year Safety and Efficacy Results	Andonian, et al	European Urology 52 (2007) 245-252
2005-01-13	Randomized Clinical Trial Comparing Suprapubic Arch Sling (SPARC) and Tension-free Vaginal Tape (TVT): One-Year Results	Andonian, et al	European Urology 47 (2005) 537—541
2007-01-01	Complications of Sling Surgery Among Female Medicare Beneficiaries	Anger, et al	Obstet Gynecol 2007;109:707—14
2010-01-01	Tension-Free Vaginal Tape Versus Transobturator Suburethral Tape: Five-Year Follow-up Results of a Prospective, Randomised Trial	Angioli, et al	European Urology 58 (2010) 671-677
2009-01-01	Tension-free vaginal tape versus tension-free vaginal tape obturator (inside-outside) in the surgical treatment of female stress urinary incontinence	Aniuliene R	Medicina (Kaunas) 2009; 45(8)
1986-03-22	Epistemology of Surgery	Anon	The Lancet
2009-01-01	The influence of BMI, smoking, and age on vaginal erosions after synthetic mesh repair of pelvic organ prolapses. A multicenter study	Araco, et al	Acta Obstetrica et Gynecologica. 2009; 88: 772—780
2008-01-24	TVT-O vs TVT: a randomized trial in patients with different degrees of urinary stress incontinence	Araco, F. et al	Int Urogynecol J (2008) 19:917—926
2012-01-01	Complications from the Placement of a Tension-Free Suburethral Sling Using the Transobturator and Retropubic Methods for Treatment of Female Urinary Incontinence	Arrabal-Polo, et al	Urologia Internationalis
2003-01-01	Randomized trial of porcine dermal sling (Pelvicol implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: a questionnaire-based study	Arunkalaivanan, Barrington	Int Urogynecol J (2003) 14: 17—23

	SINGLE-INCISION MIDURETHRAL TAPE (OPHIRA) VS TRANSOBTURATOR TAPE (OBTRYX): PROSPECTIVE COMPARATIVE STUDY- 2 YEAR FOLLOWUP	Arunkalaivanan, et al	Abstract 245
2009-01-01	Efficacy and safety of transobturator tape (Obtryx) in women with stress urinary incontinence and intrinsic sphincter deficiency	Arunkalaivanan, et al	Presentation 778
2008-00-00	Haemorrhage and nerve damage as complications of TVT-O procedure: case report and literature review	Atassi, et al	Arch Gynecol Obstet, 277(2), 161-164
2013-01-01	Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: Why do tapes fail?	Athanasίου, et al	Int Urogynecol J
2009-01-01	MIXED URODYNAMIC INCONTINENCE: TVT or TVT-O?	Athansiou, et al	Int Urogynecol J (2009) 20 (Suppl 2):S73–S239
2011-11-01	AUA Position Statement on the Use of Vaginal Mesh For the Repair of Pelvic Organ Prolapse	AUA	American Urological Association
2012-04-01	ADULT URODYNAMICS: AUA/SUFU GUIDELINE	AUA	American Urological Association Education and Research, Inc.
2009-01-01	Guideline for the Surgical Management of Female Stress Urinary Incontinence 2009 Update	AUA	
2011-11-01	AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence	AUA	
2013-01-01	Guidelines for Privileging and Credentialing Physicians for Sacrocolpopexy for Pelvic Organ Prolapse	AUGS	Female Pelvic Medicine & Reconstructive Surgery, 19, 2
2011-07-01	AUGS Response FDA Safety Communications	AUGS	American Urogynecologic Society
	Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders	AUGS	American Urogynecologic Society
2011-09-09	AUGS statement September 8-9, 2011	AUGS	AUGS
2012-01-01	Guidelines for Providing Privileges and Credentials to Physicians for Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse	AUGS	Female Pelvic Medicine & Reconstructive Surgery Volume 18, Number 4
2014-01-01	Committee Opinion: Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment	AUGS and ACOG	Female Pelvic Medicine & Reconstructive Surgery 20; 5: 248 - 251
	Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	AUGS, SUFU	

2014-01-03	Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	AUGS-SUFU	
2009-01-01	Do novo stress incontinence and pelvic muscle symptoms after transvaginal mesh repair	Aungst, et al	Am J Obstet Gynecol 2009;201:73.e1-7
2006-01-01	Vaginal erosion, sinus formation, and ischiorectal abscess following transobturator tape: ObTape implantation	Babalola, et al	Int Urogynecol J (2006) 17: 418—421
2004-00-00	Cystocele repair by vaginal approach with a tension-free transversal polypropylene mesh	Bader, et al	Gynécologie Obstétrique & Fertilité 32 (2004) 280--284
2005-10-01	Severe Mesh Complications Following Intravaginal Slingplasty	Baessler, et al	Obstet Gynecol 2005;106:713–6)
2006-01-01	Mesh augmentation during pelvic-floor reconstructive surgery: risks and benefits	Baessler, Maher	Curr Opin Obstet Gynecol 18:560–566
2006-01-01	Principles of Polymer Science, 2nd Edition	Bahadur, Sastry	
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	LONG-TERM 6 YEAR PATIENT SATISFACTION AND QUALITY OF LIFE OUTCOMES AFTER AN ADVANTAGE SLINGS FOR STRESS URINARY INCONTINENCE	Balachandran, Duckett	Abstract
2008-08-01	Prospective evaluation of the safety and efficacy of the Apogee system for treatment of vault prolapse	Balakrishnan, et al	Journal of Obstetrics and Gynaecology; 28(6): 618–620
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2013-04-06	Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence	Nilsson, et al	Int Urogynecol J (2013) 24:1265-1269
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Date	Description
2015-01-01	Gynecare TVT Obturator System Instructions for Use
2015-01-01	Gynecare TVT EXACT Instructions for Use
2015-01-01	Gynecare TVT ABBREVO Instructions for Use
2015-01-00	Gynecare TVT Instructions for Use
	Operation Abbrevio Video
2006-11-20	C4001 POLYPROPYLENE MSDS
2005-04-13	C4001 POLYPROPYLENE HOMOPOLYMER MSDS
2004-03-12	C4001 POLYPROPYLENE HOMOPOLYMER MSDS

Document Date	Testimony
4/5/2012	Deposition of Piet Hinoul
4/6/2012	Deposition of Piet Hinoul
9/12/2012	Deposition of Charlotte Owens
9/13/2012	Deposition of Charlotte Owens
5/22/2013	Deposition of Daniel Burkley
5/23/2013	Deposition of Daniel Burkley
5/30/2013	Deposition of Martin Weisberg
5/31/2013	Continued Videotaped Deposition 30(b)(6)of Martin Weisberg Volume II
6/20/2013	Videotaped Deposition of Christophe Vailhe
6/21/2013	Continued Videotaped Deposition of Christophe Vailhe Volume II
6/26/2013	Deposition of Piet Hinoul
6/27/2013	Deposition of Piet Hinoul
7/24/2013	Videotaped Deposition of David Brown Robinson Volume I
7/25/2013	Videotaped Deposition of David Brown Robinson Volume II
7/29/2013	Videotaped Deposition of Joerg Holste
7/30/2013	Continued Videotaped Deposition of Joerg Holste
8/9/2013	Continued Videotaped Deposition of Martin Weisberg Volume III
9/11/2013	Videotaped Deposition of Brigitte Hellhammer
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9/11/2013	Deposition of Daniel Lamont
11/6/2013	Deposition of Richard Isenberg
1/7/2014	Videotaped Deposition of Thomas A. Barbolt
1/8/2014	Deposition of Thomas Barbolt Volume II
1/13/2014	Deposition of Piet Hinoul
2/3/2014	Deposition of Daniel Smith
2/4/2014	Deposition of Daniel Smith
2/11/2015	Trial testimony of Katrin Elbert